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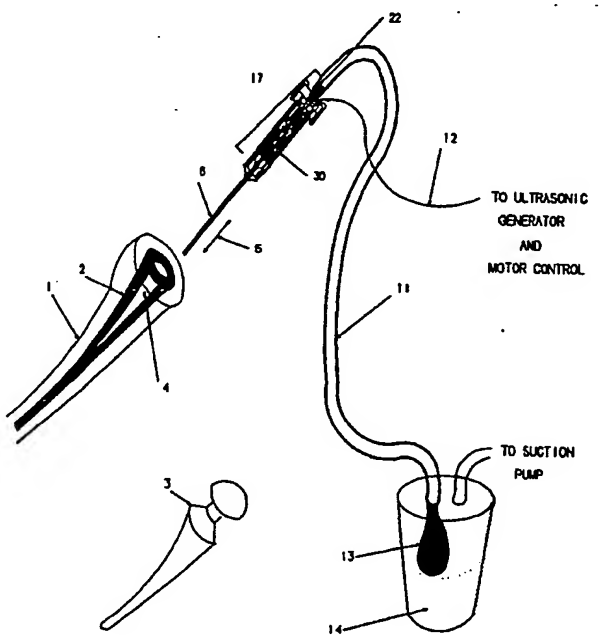
(54) Title: METHOD AND APPARATUS FOR REMOVAL OF CEMENT FROM BONE CAVITIES

(57) Abstract

A surgical method of removing cement (2) from bone cavities (4) prepared for retention of prosthetic devices (3) comprising utilization of a surgical apparatus (30) comprising a handpiece (17), a vibration source (167) within the handpiece for generating mechanical vibrations in response to current supplied thereto, and an elongated hollow tool (6) operatively associated with the vibration source and attached to the handpiece at a point extending away from the handpiece so as to contact and melt the cement (z) utilizing mechanical vibration (15). The surgical apparatus may additionally comprise concentric tubular means (62) for irrigation and suction so that the hollow tool may be cooled, the bone cavity may be debrided and the melted cement may be removed. Additional alternative embodiments of the apparatus comprise a rotational means (176, 177, 178) whereby the elongated tool may apply shear forces to the cement being removed. The apparatus may also include a telescope (87) for use as an endoscopic aspirator and a means for supplying current (107) to the elongated hollow tool for cauterizing biological material that is not removed.



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METHOD AND APPARATUS FOR REMOVAL OF CEMENT FROM BONE CAVITIES

TECHNICAL FIELD

The present invention relates to surgical techniques and procedures; in particular to methods for utilizing rotary or non-rotary aspirators for the removal of bone cement from bone canals in the replacement and repair of prosthetic bone implants.

BACKGROUND OF THE INVENTION

The use of ultrasonic vibration to enhance the performance of surgical mechanical cutting and forming implements such as saws, knives, and spatulas is generally known in the art (Goliamina, Ultrasonic Surgery, Proceedings of the Eighth Int'l Cong. on Acoustics, London, 1974 pp. 63-69). East German Patent No. 203,229 discloses an ultrasonically activated knife for general surgical application which is intended to increase both the precision and quality of incisions. The application of mechanical vibration to cutting and parting tools is therefore not new to surgical practice and has, in fact, resulted in the commercial introduction of at least one ultrasonically powered instrument for use in cutting cancellous and cortical bone.

The use of ultrasonic aspiration equipment for surgical procedures is also well known in the art. U.S. Patent 3,589,363 disclose ultrasonic aspiration for use in removing cataracts. U.S. Patent 4,223,676 relates to its use for the removal of neoplastic tissue and U.S. Patent 4,750,902 includes endoscopic procedures for bladder tumor and stone removal.

The development of prosthetic joints for the hip, knee, elbow and shoulder has offered another application for ultrasonically vibrating instrumentation. Typically, these artificial joints are cemented into a surgically created cavity in the bone. In the

case of the hip, the head and neck of the femur are removed, a cavity is reamed into the shaft and the stem of the implant is cemented into this cavity. The cement used is typically methylmethacrylate, an acrylic thermoplastic. These man made joints have an average life of about 10 years, after which they must be replaced. Usually after this time, either the implant itself loosens in the cement, or the cement becomes partially separated from the bone.

Repair of a prosthetic joint requires that first the implant be removed and then all cement be excavated from the cavity. In most cases, the implant is loose upon presentation. The cement, however, is usually found rigidly adherent to the bone. A number of powered rotary burrs have been developed to assist the surgeon in thoroughly cleaning the cavity. these burrs are effective in abrading the plastic, but, because the plastic bone cement is much harder than the surrounding cortical bone, their proper use requires extensive practice in manipulation. Cavity preparation for receiving implanted prosthetic joints may extend as much as 10 inches into bone. Guiding a high speed rotary burr tip at this distance while avoiding inadvertent contact with bone is very difficult to achieve.

Frequently, the surgeon will resort to fluoroscopy as an aid in ensuring that all the residual cement (which contains a radio-opaque material) has been removed. Even under the best of circumstances, however, some damage to adjacent bone is inevitable. Melon-ball bone pockets produced by the soft-seeking burr are a constant concern to the orthopedic surgeon because they weaken the cavity into which a new implant must be introduced.

Of all rotational skeletal attachments, the hip joint, in particular, bears the greatest portion of the human body weight. In as much as the implant procedure itself weakens the femur by creating a cavity in otherwise solid supporting physiologic matter, any additional enlargement of the original opening presents a risk of future failure, principally through perforation of the bone itself by the implant when subject to the imposed stress of therapeutic exercise or accident. Quite naturally, no surgeon welcomes a repair that, however expertly performed originally, suffers the limitations of his tools. Because access is restricted, the cement is usually firmly adherent and preservation of the remaining structural integrity of the femur is paramount. Hip revision, as this procedure in known, can require as much as 3 or 4 hours to successfully complete. Much of this time is spent in meticulously removing cement.

Recent advances in the art include ultrasonically vibrating spatulas and styluses to separate the plastic cement from the implant and the bone (Klapper and Caillouette, The Use of Ultrasonic Tools in Revision Arthroplasty Procedures, 20: 3 Contemporary Orthopaedics, pp.273-279) (March 1990). These advances exploit the inability of plastics, and particularly thermoplastics, to suffer cyclic deformation well. Metals and some ceramics have a crystalline or amorphous molecular structure that does not impede the transmission of sound waves. In plastics, however, sound transmission is always accompanied by the generation of heat. If exposed to sound pressures readily conveyed by metallic structures, such as those employed by ultrasonic dental tools and surgical aspirators, virtually all plastics will rapidly heat, melt and even vaporize.

This susceptibility of thermoplastics to intense vibration occuring at an ultrasonic frequency, is the basis of the ultrasonic plastic welding- a process widely used in industry to join molded plastic parts for a variety of uses ranging from toys to household appliances (e.g., Ensminger, Ultrasonics: fundamentals, technology, applications, pp.462-467 (1988 Marcel Dekker Inc.)). Usually, in this process, two mating halves of a plastic part are placed in contact within a nest that conforms to the surface of one of two parts joined. An ultrasonic horn, whose face conforms to the exposed surface of the other part, is then brought into intimate contact, under applied pressure, with the assembly. Vibration of the horn is transmitted to the parts. Although the entire plastic is subject to the vibration, the joint between the halves is structurally much weaker than the otherwise homogeneous portions and softens and melts well before any deformation occurs elsewhere. Once the joint melt occurs, vibration ceases, the melt recrystallizes and the bonded part is removed from the nest. Even the strongest reinforced thermoplastics can be joined in this manner within a few seconds.

Direct application of a vibrating tool will also produce local melting (Klapper and Caillouette, supra). By controlling both the contact pressure and the amplitude of vibration, softening can be modulated so that the cement can be transformed into a putty and gently released either from the implant stem or cortical bone. Because the bone is not plastic, and is, in fact, with the exception of tooth enamel, the best anatomical conductor of sound in the human body, it is not deformed by contact with the stylus. Ultrasonic vibration therefore reverses the effect encountered with rotating burrs. The ultrasonic tip

moves into the plastic far more easily than into the bone. Ultrasonic excavation is therefore much more easily controlled, even over a distance of 10 to 12 inches, and risk of inadvertent bone damage is significantly reduced when compared to the performance of instruments such as burrs which abrade rather than melt material.

The transformation of phase produced from the large cyclic strain losses in plastic, is far more localized than produced, for example, by a heated tip such as is described in U.S. Patent No. 4,873,969 to Huebsch. Because the sound waves propagate in an approximately spherical pattern, the cyclic stress levels rapidly diminish beyond the point of contact. Consequently, only the material within a few millimeters of the tip contact is softened or melted. On the other hand, a directly heated tip encounters a thermal sink in the cement which draws the energy into the entire surrounding structure. This situation dictates that inordinate amounts of energy have to be applied to obtain local melting. In the process thermal elevation of bone as well as the cement occurs. When working close to the bone, a condition that prevails in the lower one third of the cavity, the temperatures so produced can cause tissue necrosis.

The temperature at the operating tip of an ultrasonic aspirator can be controlled to a degree by a pre-aspiration device. Such a device is disclosed in U.S. patent No. 4,493,694 to Wuchinich and includes a sleeve around a central vibrating aspiration and holes in the aspiration tube communicating with the passage defined by the sleeve. Irrigation fluid is supplied through the sleeve to cool the tip and is sucked into the aspirating tube through the small holes.

Ultrasonic surgical devices have proven to provide great utility in medical surgical practice. Soft tissue is athermally dissected, leaving parent tissue undamaged. Necrosis, common to cryosurgical, electro-surgical and laser procedures is minimized in ultrasonic surgery because cell destruction is confined to a single layer. Elastic, connective tissue, however, is resistant to ultrasonic attack. For example, blood vessels having diameters larger than 1 millimeter are normally not severed by ultrasonic aspirators. In prostatectomies, the benign gland can be entirely removed without effect to the prostatic capsule (Krawitt et al., Ultrasonic Aspiration of Prostate, Bladder Tumors and Stones, Urology, 30:6 (1987) pp. 578-580). Tumors of the spinal cord can also be dissected and aspirated while preserving the anatomical and physiological integrity of adjacent neural tissue. Histologic assays of ultrasonically aspirated tissue have shown preservation of cellular morphology, enabling pathological analysis of specimens to be made with confidence (Richmond et al., Evaluation of the Histopathology of Brain Tumor Tissue Obtained by Ultrasonic Aspiration, Neurosurgery, 13:4 (1983), pp. 415-419).

As a result of the advantages attendant to the ultrasonic technique, subjects receiving such procedures have reported more rapid recovery and better retention of normal function than populations receiving conventional treatment (Malloy et al., Endoscopic Ultrasonic Aspiration of the Prostate, Bladder Tumors and Stones, Journal of Urology Supplement, May, 1989). In some cases, such as the surgical management of astrocytomas, ultrasonic aspiration is the only known method for removal that is both safe and effective (Epstein et al., Surgical Management of Extensive

Intramedullary Spinal Cord Astrocytoma in Children, Concepts in Pediatric Neurosurgery, 2, (1982) pp. 29-44). The application of this technology, initially in ophthalmic and general cardiovascular surgery, where, recently, the successful debridement of calcified heart valves has been demonstrated (Sternlieb et al., Ultrasonic Restoration of Severely Calcified Aortic Valve, The Lancet, 8/20/88, p.446).

U.S. Patent 4,750,902 includes a comprehensive review of the art and literature forming the foundation of the technology. In essentially all indicated applications, the instrumentation excites and sustains controlled extensional resonance of slender, hollow, prismatic tubes, thereby producing a standing wave whose principal attribute of interest is reciprocal motion of a surgical tip. The frequency of vibration, determined by the dimensions of the tube and the electro-mechanical transducer exciting the motion, is typically selected to lie within the range of 10 to 50 kHz (10,000 to 50,000 cycles of vibration per second). It has been discovered that, if the magnitude of the vibration is adequately large within this frequency band, the application of the tip directly to soft tissue, such as muscle, produces separation of the cellular structure at the locus of contact. The peak to peak vibration amplitude required to produce the phenomena depends upon the particular tissue under consideration, but usually lies within the range of 6 to 18 mils (0.006 to 0.018 inches or 150 to 460×10^{-6}m). If a source of vacuum is simultaneously applied to the bore of the hollow tip, tissue parted by the vibration can be separated and withdrawn into a suitable collection vessel.

The agent responsible for the observed phenomena is cavitation of intercellular water, or the

free water between cells. Cavitation is well known for causing the erosion of apparatus such as ship propellers for example. Cavitation may also be used to advantage in ultrasonic cleaning apparatus. In surgical applications, the free intercellular water enters a vapor phase, manifest as micron (10^{-6}m) sized bubbles, as the tip rapidly retracts during one half cycle of vibration. When the tip returns in the next half cycle, the bubbles collapse, producing extraordinarily high but very localized pressure. Typically, the pressures produced are on the order of one million atmospheres. Cell walls adjacent to the tip are ruptured in the process, producing the observed dissection.

Although dissection and aspiration using a blunt, hollow and intensely vibrating tube have demonstrated significant surgical utility, their use is limited precisely by the very effect they exploit: tissues having little hydration are extremely resistant to attack. For example, in surgery of the knee, where the meniscus or synovium must be partially removed to restore function following an injury, this technology currently offers no competition to the scalpels or other cutting devices available to perform the procedure. The same situation prevails regarding the discs of the spinal cord. In general, within the body, those structures intended to absorb physical abuse from exertion are difficult to excise surgically. It is in these specialties of surgical practice that ultrasonic aspiration has been notably unsuccessful

Another limitation of current ultrasonic instruments involves their restricted ability to cleanly dissect the "cores" of tissue that are produced from the parent structure. This difficulty is particularly noticeable when the subject anatomy is

perpendicular or at an acute angle to the tip. Tissue filling the tip bore can not easily be separated without angling the tip to sever the "pedestal" attachment, and, in certain procedures, anatomical restrictions do not permit such movement. An example is the aspiration of the pituitary gland, which is located at the base of the brain. The inability of the straight ultrasonic tip to completely remove this portion of the gland through an opening made in the roof of the mouth is, in part, related to its acute presentation.

Another limitation of current ultrasonic instruments is apparent in endoscopic procedures, where the surgeon's view is provided by a telescope and where perspective is extremely important. The surgeon must be able to gauge the position of the cutting implement in relation to the entire target. The spatially fixed relation between the ultrasonic tip and telescope lens such as that disclosed in U.S. Patent 4,750,902 does not provide such a perspective. A portion of the field of view is always blocked by the tip, which must, of necessity, remain visible, and it is not possible to extend the tip into the field to judge its size in relation to associated anatomy. The surgeon is thus forced to operate "right in front of his nose."

U.S. Patent 3,526,219 illustrates the evident ability of ultrasonic vibration to enhance cutting by applying vibration to a number of knife tips attached to an ultrasonic transducer. In this use of vibration, cavitation plays no rule whatsoever in dissection. It is rather the addition of reciprocal motion to the blade edge that enhances penetration into tissue. However, all ultrasonic aspirators utilize a tube whose opening is at nearly a right angle to its axis and to the direction of application. If the opening is

bevelled, penetration into tissue is facilitated but core pedestals remain more difficult to sever.

Also of interest to the surgeon is the possibility of providing an electrocauterizing radio frequency potential to the ultrasonic tip. The currents produced by such potentials, when passed from the tip through tissue to a return electrode, have long been known to effectively seal bleeding vessels. U.S. Patent 4,750,902 discloses one way for providing such potentials to the tip of ultrasonic aspirators. Others have evaluated the use of electrical coagulating currents in the endoscopic dissection of fibrocartilaginious structures of the knee (Caspari, Current Development of Instrumentation for Arthroscopy, Clinics in Sports Medicine, 6:3 (1987), pp. 626-627; Johnson, Arthroscopic Surgery: Principles and Practice (third edition), Verlag Springer (1986), pp. 244-245).

U.S. Patent 4,838,853 discloses an ultrasonic handpiece for the removal of meniscus. The hollow tip is vibrated extensionally while a source of vacuum is connected to the tip bore to remove dissected fragments.

U.S. Patent 4,504,264 discloses an ultrasonic surgical device that provides both irrigation and aspiration as well as tip rotation through a specified arc of 5 to 60 degrees. The handpiece of this patent is rather bulky and difficult to manipulate in precise surgical procedures.

Continuously rotating instruments for the removal of tissue are also shown in U.S. Patent 4,203,444, where rotation of a hollow tube within a protective sheath is used with aspiration to (1) capture tissue within a window, (2) sever the entrapped specimen by rotation of the tip and (3) withdraw the dissected tissue by vacuum to a collection container.

Rotating ultrasonic transducers are also generally known in the metal working or mineral extraction fields. U.S. Patent 3,614,484 shows a method for introducing continuous rotation into an extensionally vibrating ultrasonic transducer for enhanced machining of materials. The ultrasonic transducer is mounted to the rotating, nonvibrating frame at points where significant ultrasonic vibration is known to exist. The wear induced by this support limits the life of the appliance. More recently, U.S. Patent 4,828,052 shows an attachment to a rotating ultrasonic transducer that permits coaxial irrigation for the improved drilling of very hard materials.

Accordingly, there is a need in the art for a surgical instrument which is capable of reducing the disadvantages of current devices. In addition, there is also a need for improving current methods for removing cement from bone cavities with such instruments.

SUMMARY OF THE INVENTION

It is therefore an object of the invention to provide a method for removing cement from bone cavities which reduces the possibility of damage to the bone itself. As such, a feature of the invention is to utilize mechanical vibration to breakdown and melt the cement. A further feature is a surgical apparatus capable of applying mechanical vibration to the cement without damaging the surrounding bone if contact is made. These features have the advantage of reducing the degree of precision required by the surgeon and thereby increasing the speed and effectiveness of the procedure.

A further object of the invention is to provide a means for aspirating cement in bone cavities

with an easily manipulated surgical apparatus while simultaneously cooling and damping lateral vibrations in the apparatus. Therefore a feature of the invention is concentric means for cooling and aspiration. This allows cooling fluid to be directed precisely to the point where cooling is required, while minimizing the size of the apparatus and tool in contact with the cement. Additionally, cooling fluid may be used for irrigation if desired.

Another object of the invention is to apply shear forces to the cement being removed in order to increase the effectiveness of the removal. A feature of the invention is therefore a rotating tool with a tip shaped to shear away the cement. In this manner the rate of removal of cement may be increased without increasing the possibility of damage to the surrounding bone.

These and other objects are accomplished according to the present invention by a method of removing cement from bone cavities comprising the steps of applying an end of a elongated hollow tool, capable of mechanical vibration, to the bone cement; melting an area of cement by vibration of the tool; and aspirating the melted cement by suction applied through the tool. For certain applications, additional method steps include applying shearing forces to the cement, rotating the hollow tool in contact with the cement to apply the shearing forces, cooling and damping lateral vibration in the hollow tool and irrigating the area of melted cement.

A surgical apparatus according to the invention includes a handpiece having first and second ends with a first opening defined by the first end; an elongated hollow tool extending from the first opening for contacting the cement in a bone cavity; a vibration

source within the handpiece for generating mechanical vibrations in response to electrical current applied thereto, and aspiration means for withdrawing melted cement from the bone cavity. The vibration source is operatively associated with the elongated hollow tool and the tool is attached to the handpiece at a point where no vibration occurs.

The vibration source according to the invention includes a tubular piezoelectric crystal having a means for electrical contact, a union for connecting the crystal to the elongated hollow tool and a stem extending opposite from said elongated hollow tool. In a preferred embodiment of the apparatus the stem has a length which is not resonant at the operating frequency of the crystal, and the elongated hollow tool has a length of $\Gamma/4 + \Gamma/2$ where n is 0 or an integer and $\Gamma = f/c$ where f is the frequency of operation and c is the velocity of extensional waves in the elongated hollow tool.

In one alternate embodiment of the apparatus according to the invention a rotation means is operatively associated with the vibration source for rotating the elongated hollow tool about its longitudinal axis through at least one revolution, said rotating means enabling the elongated hollow tool to apply shear forces to the cement. The tool may be provided with a reduced opening at the end for contacting the cement and further may be cut to form a semicircular trough having longitudinally running edges for shearing the cement.

Another alternate embodiment of the surgical apparatus includes means for cooling the elongated hollow tool. In a preferred embodiment the cooling means comprises a hollow sleeve surrounding the elongated hollow tool defining an interspace between

the tool and sleeve, and a hollow tube disposed inside the stem defining a second interspace between the tube and stem. The sleeve communicates with the first opening in the hand piece. While the tube communicates with the central passage in the union member for the passage of aspirated material therethrough. The second interspace communicates with the first interspace through cooling ports defined by the union member for the passage of cooling fluid therethrough. At the working end of the hollow tool the interspace communicates with the interior of the hollow tool at a point inside the end of the sleeve.

In another alternative embodiment, the elongated tool means includes a bevelled tip for providing increased shearing of biological material. Alternatively, the elongated tool means may include a closed tip portion having at least one aperture spaced therefrom to form a window in the tool means which facilitates further in the removal of biological material.

The surgical apparatus may also include a support structure located within the handpiece for mounting the vibration source and rotating means for independent longitudinal movement relative to the handpiece. This vibration source preferably includes a piezoelectric crystal having electrodes on inner and outer surfaces thereof; a union for connecting the crystal to the elongated tool means; and a stem extending towards the rotating means. The crystal may be tubular or in the shape of a disk. The rotating means comprises a motor for generating rotational forces and means for transmitting the forces to the vibration source stem and to the elongated tool means for rotation thereof in either clockwise or counterclockwise directions. The stem preferably has a

length which is not resonant at the operating frequency of the crystal, and the elongated tool means has a length of $\Gamma/4 + n\Gamma/2$ where n is 0 or an integer and $\Gamma = f/c$ where f is the frequency of operation and c is the velocity of extensional waves in the tool means.

In another embodiment, an elongated sheath is provided for surrounding the elongated tool means. Here, the instrument advantgeously includes means for viewing the work site from the handpiece, so that the instrument can be used as an endoscopic device. The viewing means may further comprise means for illuminating the work site to facilitate viewing thereof. The viewing means may also be located within the sheath to reduce the overall size of the working end of the device. Also, the sheath may include a hood member at the forward end thereof to assist in obtaining an unobstructed view of the work site through the viewing means.

A further embodiment of the invention relates to a surgical instrument comprising a handpiece; a vibration source within the handpiece for generating mechanical vibrations in response to current supplied thereto; elongated tool means operatively associated with the vibration source and attached to the handpiece at a point where essentially no vibrational motion occurs and extending away from the handpiece to a work site whereby vibration of the tool means causes disintegration of hydrated biological material; a support structure located within the handpiece for mounting the vibration source and capable of independent longitudinal movement relative to the handpiece; means for longitudinally reciprocating the support structure and elongated tool means towards and away from the work site independently of moving the handpiece; means for irrigating the work site with

fluid to assist in withdrawing removed biological material therefrom; and aspiration means for withdrawing irrigation fluid and removed biological material from the work site.

In yet another embodiment, the previously described instrument may further include means for rotation of the elongated tool means for assisting in the removal of non-hydrated biological material. In addition, electrocauterizing means and viewing means may be incorporated into this instrument, the latter to convert it to an endoscopic device.

BRIEF DESCRIPTION OF THE DRAWINGS

The features and advantages of the invention will be more readily apparent from the following detailed description of the invention illustrated in the drawing figures, wherein:

FIG. 1 is a schematic illustration of one embodiment of the apparatus and method according to the present invention, with the apparatus illustrated in cross-section;

FIG. 2 is a cross-sectional view of an alternate embodiment of the apparatus of the invention;

FIG. 3 is an enlarged cross-sectional view of a portion of the apparatus shown in FIG. 1;

FIG. 4 is an enlarged cross-sectional view of a portion of the apparatus shown in FIG. 2;

FIGS. 5a and 5b are perspective views of two possible end embodiments for the apparatus of FIG. 1;

FIG. 6 is a section view of a tip end embodiment for cooling and damping lateral vibrations of the tip end;

FIG. 7 is a side view, partially in cross-section, of a surgical instrument in the form of an

endoscopic ultrasonic rotary electro-cauterizing aspirator according to the present invention;

FIG. 8 is an enlarged side view, partially in cross-section, of the ultrasonic and rotational components of the aspirator of FIG. 7;

FIG. 9 is an enlarged side view, partially in cross-section, of a handpiece for the aspirator of FIG. 7;

FIG. 10 is a schematic illustration of a preferred tip for the aspirator of FIG. 7 along with a stress profile along such tip;

FIG. 11 is a side view, partially in cross-section, of another preferred tip for the aspirator of FIG. 7 which is specifically designed for use in arthroscopic surgery;

FIG. 12 is a series of illustrations depicting tissue dissection according to the aspirator of the present invention compared to prior art devices;

FIG. 13 is a schematic view of the aspirator of FIG. 7 along with related instrumentation prepared for surgery;

FIG. 14 is a side view, partially in cross-section, of a modification of the aspirator of FIG. 7, whereby aspiration can be conducted through the irrigation port;

FIG. 15 is a schematic of the preferred tip for the aspirator of FIG. 7 illustrating the components of velocity produced thereby; and

FIG. 16 is a side view, partially in cross-section, of another endoscopic ultrasonic aspirator having a flexible shaft drive and utilizing side aspiration.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

While ultrasonic vibration is eminently suited for liquifying bone cement, the object of its application is the removal of the cement from the bone cavity. Application of vibration alone can convert the otherwise rigid plastic to a flowable material, but to fully exploit the phenomena, a method of transporting the liquid cement from the bone to a repository must be introduced.

Referring to FIG. 1, the general apparatus and method according to the invention is described below. Femor 1 is shown following removal of the prosthetic implant 3. A cavity 4 remains whose walls are lined with cement 2. This cement is excavated by the apparatus 30 having a hollow ultrasonic tip 6 that vibrates in the direction indicated by arrow 15. The tip 6 is an elongated hollow tool which is attached to handpiece !7. The apparatus 30 illustrated in FIG. 1 is one embodiment of the invention. The handpiece 17 corresponding to this embodiment is shown in detail in FIG. 3. An alternate embodiment of the apparatus according to the invention is shown in FIG. 2 and is designated 30a. The handpiece 17a corresponding to apparatus 30a is shown in FIG. 3. It will be readily appreciated by those skilled in the art that apparatus 30 in FIG. 1 may be replaced by apparatus 30a with little modification to the remaining parts. The required modification will, however, be discussed below.

Of particular interest is the form of ultrasonic motion along the transducer and tip. FIG. 2 shows both extension (peak vibration amplitude) and accompanying stress (force per unit area) within the component part of the transducer and tip 6. The direction of vibration relative to the assembly is indicated by arrow 15. Note that the stem 34, which

extends from the union 32 at a point of diminished vibration, does not vibrate. The assembly of the transducer and tip are resonant as an entity at the design frequency of vibration. At points along their structure where there is little or no vibration, called the "nodes" of motion, mounting to a rigid structure such as a housing may be accomplished without impeding vibration. The magnitude of ultrasonic vibrational velocity is extremely significant. For example, a 0.001 inch peak to peak excursion at a frequency of 20 kHz has a root mean square velocity of 44 inches per second or 2.5 miles per hour. It is therefore important, if wear and the production of heat are to be minimized, that parts of the transducer in contact with stationary structures exhibit very low levels of motion. The stem, being of a length that is not resonant at the operating frequency is one such location. The 0-rings on the union are another example. The raised portion of tip 50 is another node where support of the sleeve 62 can also be obtained. Note that the tip may not contact the sleeve at any point other than modal sleeve support 60 to prevent the inordinate production of heat.

The length and connection of the stem to the transducer is an important aspect of the design. Because the stem is not resonant in and of itself at the chosen operating frequency, and because it is attached to the transducer at a point of vanishing ultrasonic displacement, it has no effect upon the vibrational characteristics of the transducer and tip. Furthermore, by the same reasons, the entire stem is stationary, making connection to the motor shaft possible, if desired. If, in fact, the stem length were F/4, where F is the wavelength of extensional waves, or was, whatever its length, attached at a point

on the transducer exhibiting significant ultrasonic motion, vibration would exist at the motor shaft connection, satisfactory operation could not be sustained. The motor bearing, windings and insulation would be rapidly degraded under vibration at ultrasonic frequencies. The absence of vibration on the stem also permits use of a conventional support bearing 5 for the transducer.

Although the tip is 3/4 of a wavelength, Γ, long, it may be of any length that satisfies the boundary conditions: i.e., (1) vanishing motion at its point of attachment to the transducer union and (2) vanishing stress at its open end. Solution of the wave equation for a uniform prismatic tube, subject to these conditions, dictates that the tip length, L, be such that

$$L = \Gamma/4 + n\Gamma/2 \qquad (1)$$

wherein n an integer (0,1,2...) and $\Gamma = f/c$ where f is the frequency and c is the velocity of extensional waves in the tip.

The releasable tip is shown attached at a quarter wavelength point on the transducer so as to take advantage of the large difference in cross-sectional areas between the transducer and tip to produce an increase in vibrational amplitude. It can be shown, for such a structure, that this increase or gain, G, can be expressed as

$$G = (\sigma_e c_e S_e)/((\sigma_t c_t S_t) \qquad (2)$$

where σ is the density, c is the sound velocity and S is the cross sectional area. The subscript e and t refer to the effective values for the transducer and tip respectively. If this reduction in cross sectional area is not made, the motion produced by the transducer will not be sufficient to dissect tissue. Typically, piezoelectric transducers can produce about 0.001 inch

peak to peak displacement at a frequency of 20 kHz. With the reduction at the Γ/4 point, the tip end displacement can easily attain 0.001 to 0.020 inch, peak to peak.

The apparatus according to the present invention is generally constructed in accordance with the principles of U.S. patent application serial no. 07/439,114, filed November 17, 1989, the content of which is expressly incorporated herein by reference thereto.

FIG. 3 shows the ultrasonic and rotational components of the apparatus. FIG. 4 shows an embodiment of the invention which does not utilize the rotational aspects of the invention, however, like numerals refer to like parts in both FIGS. 3 and 4. The ultrasonic transducer assembly includes a union 32 where the surgical tip 6 is attached. This union is integral with a stem 34 which enters a motor coupling 16. The free end of the stem 34 terminates in a fitting 22 permitting the attachment of tubing 11. In both apparatus 30 and 30a the fitting does not rotate. A spindle 36 is attached to the union 32 by threads and, with the use of the prestress nut 38, holds the assembly together under the extension and contraction of vibration. Optional ceramic insulator rings 40 are sandwiched on each side of the tubular piezoelectric crystal 10.

The crystal 10, typically made of polycrystalline zirconium titanate, contains electrodes covering its inner 42 and outer 44 surfaces, with the inner electrode wrapped around the left edge and onto the outer diameter. An electrical insulation air gap 46 separates the inner electrode from the spindle 36. In FIG. 3, brushes 7 are held in contact with these electrodes by springs. Because the embodiment shown in

FIG. 4 does not rotate, the electrical connections 7 are direct to the crystal 10, without the need for electrodes 42 and 44. In crystals of the type shown, a voltage applied between the electrodes produces a change in the axial length of the tube, thereby supplying the means for exciting vibration.

The stem 34 does not vibrate so that it can be attached to an electric motor 9 as shown in FIG. 3 through an insulated motor coupling 16. The motor 9 may be any one of a number of types such as a stator winding 48 and an armature 50 which rotates. Bearings 52 support the rotation of the armature within the motor housing 54. The transducer is driven in rotation by the motor 9 through the coupling 16 and is itself supported on a bearing 8 and O-ring seals 56. The embodiment shown in FIG. 4, of course, does not employ a motor because rotation is not required.

The insulating materials employed should have dielectric properties approaching that of a vacuum. The material for insulator ring 40 should also have acoustic properties approaching or exceeding those of the piezoelectric material 10, since these rings are exposed to large cyclic stress at the frequency of vibration. For example, nylon may be used for the insulating material 16 of the coupling which is not subject to vibration, but a ceramic such as MACOR (Trademark of Corning Glass Works, Corning, NY), which exhibits both a dielectric constant only several times that of free space, and elastic losses typical of metals, is preferably used for the insulator rings 40. Exposed to the magnitude of cyclic stress generated by the transducer (i.e., about 3,000 pounds per square inch) at a frequency of 10-50 kHz, virtually all common plastics will melt or decompose.

Insulation of the piezoelectric crystal 10 from all other electrically conductive components also isolates the ultrasonic generator supply from the surgical tip 6, thereby ensuring that no unintentional currents flow through the subject. Although it is possible to isolate the ultrasonic generator from its supply of operating room utility current, the insulator rings 40 preferably afford additional and usually the desired level of protection.

Referring again to FIG. 1, the tubing 11 is connected to a vacuum canister 14 which serves as a receptacle. This canister is connected to a source of suction. The suction source may be provided by standard wall connection to a central operating room vacuum system or to a separate, regulated, suction pump. An optional trap 13 may be used to collect solid matter passing through the tubing.

As discussed previously, the alternative embodiment of the apparatus 30a shown in FIGS. 2 and 4 does not employ rotation of the tip 6. The apparatus 30a as shown is, however, designed for concentric cooling, damping of lateral vibration and aspiration. Cooling and damping are optional in application and it will also be readily apparent to those of ordinary skill in the art that the feature of concentric cooling, damping and aspiration could be equally applied to the embodiment of the apparatus 30 employing a rotating tip.

As can be seen best in FIG. 4, aspiration occurs through the tip 6 which is formed with the union 32. An aspiration tube 21, inside stem 34 communicates with the tip 6 through union 32. Cooling and damping flow is admitted to an interspace 64 between a sleeve 62 and the tip 6 by ports 66 drilled at right angles through the end of the transducer coupled to the tip 6.

The sleeve 62 is supported by the nodal sleeve support 60 at a point where no vibration of the tip occurs. A flexible tube similar to tube 11 shown in FIG. 1, but allowing for both aspiration and cooling and damping flow in a concentric arrangement as indicated in FIG. 4, is attached to fitting 22.

In addition to cooling the tip 6 the cooling flow is employed to damp excessive vibration at the end 5 of tip 6. Cooling and damping may be achieved with the tip end 5a, shown in FIG. 6. Trough 19a extends back and into the opening defined by sleeve 62. This allows a free flow of cooling fluid from interspace 64 into the tip 6 without contacting end 5a and obscuring the surgeon's vision of the work area. In addition to cooling the tip 6, the tip end construction shown in FIG. 6 performs an important function in minimizing lateral vibration of the tip end 5. The fluid in interspace 64 surrounds the tip at the end and thus acts as a buffer against lateral vibration.

The location of the back of trough 19a may be varied to control the amount of cooling fluid entering the tip 6 at that point. In this manner, and by controlling the overall flow of the fluid, the cooling fluid may be also utilized for irrigation if desired.

In operation the handpiece is connected by cable 12 to a source of ultrasonic frequency electrical current to power the transducer and in apparatus 30, and run the motor 9. The vibrating tip is then applied to the rim of cement 2. The application locally melts the cement material 2 which is then drawn into the tip 6 by the applied suction. Within the tip 6, the cement recrystallizes into a solid sliver which is then deposited in the vacuum canister 14. Because the cement 2 rapidly reforms into a solid, the end 5 of the ultrasonic tip 6 has a reduced opening as shown in FIG

5a. This reduction prevents cement from lodging within the tip 6 since it is excavated by an annulus having a smaller diameter than the ensuing conduit.

In the rotating embodiment, apparatus 30, the end 5 may also be semicircular 19 in cross section as shown in FIG. 5b. Since the tip may be rotated by the motor, such a modification nevertheless results in effective liquefaction and aspiration. However such a tip possessing, as it does, edges parallel to the axis of the tip, exposes the cement to shearing as well as extensional vibration. In some instances, this shearing or cutting action is extremely effective in rapidly dissecting the cement.

The preferred range of ultrasonic frequencies employed by this invention is from 10 to 50 kHz. The magnitude of tip vibration suitable for cement removal extend from 0.001 to 0.020 inches peak to peak. The tip 6 may be a one quarter wavelength long or one quarter plus a integral multiple of one half wavelength long. For example, if the tip 6 is titanium and the frequency of operation is 20 kHz, the tip may be 2.5, 7.5, 12.5, etc. inches in length. The opening at tip end 5, through which the melted cement passes, may be as small as 0.062 inch or as large as one half inch.

As is apparent from the alternate embodiments, arthroplasty using this invention does not necessarily require the use of rotation. Even with apparatus 30 the motor may be deactivated while the ultrasonic transducer is energized. In some instances, however, rotation will result in more rapid and effective removal of the cement, particularly in those regions near the bone. In these situations, the semicircular tip may be employed to assure complete exposure of all edges, both those producing vibrational shear and those producing extension, to the cement over

a complete revolution of 360 degrees. When rotation is used, the preferred rate lies between 0.001 and 10,000 rpm.

Also as discussed above, the tip length of apparatus 30a may be any odd multiple of a quarter wavelength. Therefore, if the frequency of operation is 20 kHz and if the tip is made of titanium, the tip may be 2.5, 7.5, 12.5, etc. inches long. The range of tip vibrational movement is 0.001 to 0.02 inches peak to peak, at 20 kHz.

In addition, the surgical devices of the invention can be used in endoscopic procedures other than arthroplasty, one such procedure being the endoscopic dissection and removal of diseased or otherwise unwated biological material or tissue.

FIG. 7 illustrates the surgical device of the invention in its preferred form as an endoscopic ultrasonic rotary electro-cauterizing aspirator apparatus. This apparatus includes a handpiece which houses the ultrasonic and rotational components and provides a handgrip 93 for the user, an elongated extension including a working tip 123 capable of vibrating and rotating for dissection of tissue, viewing means in the form of a telescope 87 extending form the rear of the housing to the working tip, a light source 89 for providing illumination to areas adjacent the working tip 123, an aspiration fitting 90 which communicates with the internal bore of the working tip 123; an irrigation valve 95 for introducing fluid to the working tip 123, and a thumb trigger 91 attached to the ultrasonic and rotary component support for reciprocating the working tip 123 linearly forward and backward. Each of these components is described in further detail hereinbelow.

FIG. 8 shows the ultrasonic and rotational components. The ultrasonic transducer assembly includes a union 78 where the surgical tip is attached. This union is integral with a stem 68 which enters a motor coupling 67. A spindle 69 is attached to the union 78 by threads and, with the use of the prestress nut 72, holds the assembly together under the extension and contraction of vibration. Ceramic insulator rings 70 are sandwiched on each side of the tubular piezoelectric crystal 76. The crystal 76, typically made of polycrystalline zirconium titanate, contains electrodes covering its inner 74 and outer 73 surfaces, with the inner electrode wrapped around the right edge and onto the outer diameter. An electrical insulation air gap 77 separates the inner electrode from the spindle 69. Brushes 79 are held in contact with these electrodes by springs 80. In crystals of the type shown, a voltage applied between the electrodes produces a change in the axial length of the tube, thereby supplying the means for exciting vibration.

The stem 68 does not rotate so that it can be attached to a motor 81 through the insulated motor coupling 67. The motor may be any one of a number of types such as a stator winding 84 and an armature 83 which rotates. Bearings 82 support the rotation of the armature within the motor housing 81.

Insulation of the motor armature 83 and tubular piezoelectric crystal 76 from the union 78, stem 68, and spindle 69 is necessary when electrocauterizing current is to be applied independently of rotation or vibration. The radio frequency voltages normally employed in electro-cautery generators exceed 1,000 volts, a level that can easily interfere with the normal operation of motors and transducer power sources.

Insulation of the piezoelectric crystal 76 from all other electrically conductive components also isolates the ultrasonic generator supply from the surgical tip 98, thereby ensuring that no unintentional currents flow through the subject. Although it is possible to isolate the ultrasonic generator from its supply of operating room utility current, the insulator rings 70 preferably afford additional and usually the desired level of protection.

The motor shown may operate as a polyphase induction machine or, with provision for a commutator on the armature shaft, as a direct current machine. If the motor is operated by alternating current, speed control is effected by a variation in the frequency and magnitude of the stator current. If the motor is a dc machine, speed control is achieved by a change in the magnitude of either or both the stator or armature currents.

The motor may also be driven by a supply of compressed gas. Where such motive power is used, the cable connecting the motor to its control and power unit contains, in addition to electrical wires for powering the transducer and electrifying the tip, flexible hoses for admitting and discharging the compressed gas. Because the instrument itself must remain sterile in use and is operated in a sterile field, spent gas exits at point remote from the handpiece.

The motor may also be located within a control and power unit and connected to the transducer stem 68 by a flexible shaft that can accommodate rotation. Such shafts are commonly available for rotating hand tools and are used extensively in such devices as automobile speedometers. Placement of the motor outside of the handpiece not only reduces the

weight of the instrument, but also shortens the length of the handpiece. Both modifications assist the surgical procedure by reducing operator fatigue and improving manipulation of the apparatus. When a flexible shaft is utilized, aspiration must be implemented at another point on the handpiece to preserve sterility of dissected tissue.

Instead of the structure shown in FIG. 8, other designs are available to produce the requisite tip excursion. The principle of quarter wavelength amplification, through a change in cross sectional area, material or both variables, is preferred for converting modest transduced displacement to levels sufficiently intense to perform the intended work.

Furthermore, although the tip is shown as a tube with uniform cross section, it is also possible to contour its shape to achieve additional motional intensity at its open end. Such alternate shapes are shown in U.S. Patent 4,750,902 and are expressly incorporated herein by reference thereto. Exponential, catenoidal and gaussian tapers, subject to design at the specified frequency, therefore constitute alternative and equally useful embodiments.

The handpiece shown in FIG. 9 comprises both an inner moveable (but not rotatable) housing 116 and outer stationary housing 103. Cavities 110 support the transducer brushes. Spring contact 109 conveys electro-cauterizing current through bearing 71 to the stem 68 and thereby to the tip 117. The bearing is a convenient device for introducing electro-cauterizing current, but this current can also be supplied by brush contact on the stem itself or between O-rings 75 on the transducer. Entrance 107 in the inner housing is a passageway for the motor wiring. Electrical connection to the transducer brushes,

bearing and motor are made to cable 106 which enters a milled channel in the linear housing.

Movement of the inner housing along the axis of the handpiece is accomplished with a moveable thumb trigger 91 attached to the inner housing and a stationary finger grip 93 connected to the outer housing. Bellows seal 111 connects the inner and outer housings, both of which do not rotate, permitting axial motion of the inner housing while preventing irrigation fluid from entering the handpiece. The transducer O-rings 75 also provide a rotating seal for preventing entry of moisture. Seal 115 is a gasket placed in a groove in the outer housing to prevent fluid from entering the housing in the vicinity of the trigger mechanism 91. This seal is of a purely sliding type.

Aspiration is performed through the stem 68, the coupling 67 and the motor armature 83. The left most portion of this armature exits the outer housing through O-ring seal 105 which again acts to exclude fluids from the handpiece. This seal is both a rotating and sliding barrier, since operation of the trigger moves the inner housing and all of its contained components.

Axial movement of the inner housing is limited by slot 102 on the outer housing and pin 101 on the inner housing, respectively. This mechanism also prevents rotation of the inner housing which would otherwise occur as a reaction to the torque of the motor armature. The rear bulkhead 112 which contains the aspiration fitting 90 and electrical cable 100 is sealed to the outer housing by nut 114 and fitting 113 which is permanently attached to outer stationary housing 103.

Although fluid seals on parts of the housing not in contact with irrigating or body fluids are not

essential for operation of the instrument, they are a practical necessity. All surgical instruments must be designed to withstand sterilization by steam or immersion in room temperature cleaning or sterilizing solutions. If water vapor or solution enters the interior of the handpiece, contamination of electrical and mechanical components can place the surgeon and the patient at risk, either from electrical shock or through iatrogenic injury caused by attempts to use an improperly operating handpiece.

A medical telescope 87 may be attached to the handpiece as shown in FIG. 7. This telescope permits the surgeon to view the procedure from a point outside of the body. The telescope assembly preferably is integral with the sheath 97, and attaches to the handpiece to nut 149 with a self-locking taper fitting 146 and retaining pin 147. The optical components include the eyepiece, relay lenses 88, 94, prisms 96 as well as a fiber optic illumination cable 92 and fitting for attachment of a light source 89. An insulated hood 98, bonded to sheath 97, separates adjacent, but physically different tissues, thereby assisting the surgeon in obtaining an unobstructed view of the surgical site. The importance of this hood in obtaining a clear perspective view of the surgery, especially in tightly confining tissue cavities cannot be over-emphasized.

Irrigation is provided to the tip 123 by valve 99 which enters the outer housing and contains a luer fitting for connection to a source of fluid. It is noted that although aspiration is shown coaxially applied, it is also possible, where a motor is not provided with a hollow shaft, to aspirate through irrigation fitting 95. This can be accomplished by

modifying the transducer union as discussed below with respect to the device of FIG. 14.

FIG. 11 shows a tip intended for use in arthroscopic surgery. The tip sheath 148 replaces the telescope and its sheath 97 of FIG. 7, and attaches to the outer housing using the identical self-locking taper. In arthroscopic procedures, the telescope is inserted through a separate opening in the knee. A layer of electrical insulating material 118, such as polyurethane, is bonded to the inner diameter of the sheath. To withstand the forces imposed by surgical manipulation of the instrument, sheath 97 is made of metal tubing and, as such, constitutes an electrical conductor. Without insulation, electrocauterizing current, destined for tissue in contact with the end of tip, might flow via tip-sheath contact to unintended anatomy. This insulation may also be present in the sheath shown in FIG. 7. A window in the sheath allows tissue to be drawn into the tip which itself has a bevelled terminus. Material so captured by vacuum applied to the tip bore is then severed by tip rotation 120 and vibration 121. Although FIG. 11 illustrates a bevelled tip, the invention may utilize any of may tips developed for arthroscopic rotating dissectors, including "window" and the "serrated window" configurations shown, for example, in U.S. Patent 4,203,444, and expressly incorporated herein by reference thereto.

The improvement in tissue dissection to be obtained from the present apparatus is illustrated in FIG. 12. The upper row of drawings depict an attempt to dissect tissue using a conventional, non-rotating aspirator tip. At time 0, the vibrating tip enters and begins separating targeted structure. Dissection of a tissue core proceeds at time 1. To sever the segment,

the surgeon lifts the tip at time 2 and tries to part the base of the core or pedestal. In doing so, the lower edge of the tip is forced against the base which results at time 3 in release of the entire segment which remains attached to the parent tissue.

A rotating ultrasonic aspirator is shown attempting the same procedure in the lower row of FIG. 12. Again, segment formation occurs at times 0 and 1. The tip then rotates and proceeds with progressive dissection. However at time 2, the pedestal is severed by rotation of the bevelled tip, enabling the tangential component of motion present on edge to complete the dissection, resulting in complete retention of the tissue within the tip at time 3.

The method of providing rotation is not limited to any specific range of speed or direction. For example, the motor may be capable of operating from 0 to 200 rpm (revolutions per minute) or, with appropriate bearings to as much as 3,000 rpm. The direction of rotation may also be reversed without affecting the rate of tissue dissection. In fact, it may be advantageous to periodically reverse rotation when severing certain tissue structures exhibiting asymmetrical morphology that are more easily separated from one side that from the other.

In general, rotation reversed through arcs of from 61 to 360 degrees is found sufficient for most purposes, but rotation through any arc is possible through appropriate control of the motor.

The components of ultrasonic velocity at the working tip of the apparatus are shown in FIG. 15. V is the extensional velocity of the tip surface and is equal to $2\pi FE$, where f is the frequency of vibration and E is the peak displacement amplitude. Vn is the component of velocity normal to the edge and is the

agent responsible for producing cavitation of intercellular free water. Vt is the tangenital velocity component of the edge whose action is to sever tissue by shear. Vn and Vt are related to V by

$$Vn = V\cos\alpha \quad \{3\}$$

$$Vt = V\sin\alpha \quad \{4\}$$

where α is the bevel angle defined in FIG. 15. When α is 45 degrees, for example, Vn equals Vt. At this angle the cavitational and shearing effects are produced by equal velocities. To Vn and Vt must be added components of the rotational velocity Vr. However, because rotation can not be reversed at rates approaching ultrasonic frequencies, Vr is unidirectional, and not reciprocal, within one cycle of vibration, and therefore does not augment cavitation. The tangential component of Vr does introduce a steady shearing velocity to the tip edge upon which the alternating component, Vt, is superimposed, but the principal function of Vr is to simply ensure that tissue is exposed in its entirety to Vt.

The handpiece is shown with its related instrumentation prepared for surgery in FIG. 13. The control unit contains a handpiece connector 129 which supplies appropriate electrical voltages and currents to motor wires 142, ultrasonic transducer lines 143 and electrosurgical conduit 141 from respectively, motor control and speed adjustment 126, ultrasonic generator control and adjustment 127 and electrosurgical generator control and adjustment 128. A footswitch 133, which activates the vibration, rotation and electro-cauterization functions, is also connected to the control unit by connector 140. Electro-cauterizing

current is returned through the patient into electrode 134 and thus to the generator via connector 139. A fiber optic illumination source and intensity adjustment 136 is connected to the telescope fitting 89 by cable and connector 135.

Aspiration is accomplished by connection of a vacuum canister 131 to a source of suction 130. This canister contains a specimen trap 132 which communicates directly with tubing entering a pinch valve 138 on the control unit. This valve, when opened, applies vacuum to the aspiration line connected directly to the fitting 90 shown in FIG. 7.

Irrigation is provided from a reservoir 137 suspended at some fixed height above the patient. This canister contains a fluid suitable for performing the procedure. For example, the solution may be glycine for urologic applications, or saline or distilled water for arthroscopic operations. Valve 95 admits or stops the flow of irrigant into the sheath, over the tip and into the surgical site.

In use, the surgeon inserts the sheath 97 into a natural or surgically introduced orifice. He then adjusts irrigation flow by the position of valve 95 or solution reservoir canister height to obtain adequate visibility. Operation of the footswitch in combination with adjustments on the control unit permits vibration amplitude and rotational speed to be selected for optimum tissue dissection rates. Electro-cauterizing current can be applied to the tip as needed again with use of the footswitch. The lower footswitch pedal in FIG. 13 has three positions. The first opens the aspiration pinch valve, the second activates ultrasonic vibration and the third rotates the tip. The upper footswitch pedal controls applications of electro-cauterizing current.

An important feature of the invention is the ability to independently operate all modalities: suction, vibration, rotation, electro-cauterization and tip extension and retraction. The footswitch shown is only one example of a convenient method for combining the separate functions.

It is noted that the invention is not restricted to use of motors with hollow shafts. In some instances, gear trains are fitted to motors that do not have a concentric passageway. By modifying the transducer as shown in FIG. 14, it is possible to aspirate through irrigation port 95 by connecting it to a source of vacuum. The aspiration passage in the transducer, shown continuous in FIG. 8, is terminated 170 in FIG. 14. Dissected tissue proceeds through the tip and encounters cross hole 169 and proceeds 171 to the port.

FIG. 14 also shows an alternative use of piezoelectric material. Rather than a tube, this crystal is a disk 167 whose electrodes are plated on opposite faces. The faces abut metallic rings 166 which are insulated from the rest of the transducer by ceramic spacers 168. the brushes contact these rings and so excite the crystals. In crystals of this type, a voltage applied between the electrodes produces a change in thickness, again exciting extensional vibration.

The size of the sheath is preferably about 95 french for passage through most natural body openings. Also, this relatively small size allows surgeons to create smaller surgical openings when the device is to be used for application in knee surgery, for example. The present apparatus is ideally suited for cutting meniscus in artroscopic procedures.

FIG. 16 illustrates the use of a motor externally connected to the handpiece through a flexible cable which rotates the ultrasonic transducer. The cable itself 177 consists of a flexible, but stationary, conduit 179 for confining and protecting a flexible shaft 178 preferably made of multi-stranded wire which is capable of transmitting rotation through the curved path defined by the conduit.

The conduit is releasbly connected at one end to the motor housing and at its other end to the handpiece rear bulkhead 212 by means of a retaining collar 181, cemented or otherwise permanently attached to the conduit, sandwiched between a nut 180 and the housing.

Outside of the handpiece, the flexible shaft is connected to the armature of the motor. This cable enters the handpiece through the conduit and is terminated in the pin engagement shown as 182. This engagement contains a pin 183 whose shape is square, rectangular, oval or of a shape that when inserted into a mating cavity 182 communicates rotation to the insulated coupling 187, while allowing for relative axial displacement of the pin and cavity. The chuck, which contains the cavity, is supported on bearings 186 which accommodate thrust and other forces produced by flexure of the cable upon the engagement. Since the pin is free to slide axially within the cavity, the ultrasonic transducer and tip may be displaced axially by operating the thumb and finger trigger while rotation is maintained by the motor.

With the exception of coaxial aspiration, all previously mentioned functions of the device are preserved in this embodiment. Because sterile fluids and tissue are aspirated by the tip and their sterility under conveyance to a collection vessel must be maintained, aspiration is performed in the device of

FIG. 16 through a cross hole in the transducer union whose function is illustrated in detail FIG. 14. Thus in FIG. 16, the stem of the transducer is shown as a solid.

While it is apparent that the invention herein disclosed is well calculated to fulfill the objects above stated, it will be appreciated that numerous modifications and embodiments may be devised to those skilled in the art, and it is intended that the appended claims cover all such modifications and embodiments as fall within the true spirit and scope of the present invention.

CLAIMS

What is claimed is:

1. A method of removing cement from bone or bone cavities containing same which comprises:

applying mechanical vibrations to cement present on a bone or bone cavity of a subject to melt an area of the cement by vibration; and

removing the melted cement from the bone or bone cavity by suction or aspiration.

2. The method of claim 1 which further comprises shearing the cement from the bone or bone cavity.

3. The method of claim 2 wherein the cement is sheared while the mechanical vibrations are applied to the bone or bone cavity.

4. The method of claim 1 which further comprises collecting the melted cement after removal from the subject bone or bone cavity.

5. The method of claim 1 which further comprises irrigating the cement and bone or bone cavity to assist in the removal of the cement.

6. The method of claim 1 wherein ultrasonic mechanical vibrations are applied to the cement essentially simultaneously with the suction or aspiration to assist in the removal of melted cement.

7. The method of claim 1 which includes the steps of:

applying an end of a elongated hollow tool, capable of mechanical vibration, to the bone cement;

melting an area of cement by vibration of said tube; and

aspirating the melted cement by suction applied through said tube.

8. The method of claim 7, wherein the elongated hollow tool applied to the cement is a part of a surgical apparatus, said apparatus further comprising:

a handpiece having first and second ends with a first opening defined by the first end and said tool extending from said first opening;

a vibration source within the handpiece for generating mechanical vibrations in response to electrical current applied thereto, said vibration source operatively associated with the elongated hollow tool with said tool being attached to the handpiece at a point where no vibration occurs; and

aspiration means for withdrawing melted cement from the bone cavity, so that the method steps include controlling the application of the vibrations.

9. The method of claim 8, wherein the apparatus further comprises rotation means operatively associated with said vibration source for rotating the elongated hollow tool about its longitudinal axis through at least one revolution, said rotating means also enabling said tool to apply shear forces to said cement, and wherein the method steps include rotating said tool to apply shearing forces to the bone cement.

10. The method of claim 9, which further comprises selecting the opening of the elongated hollow tool at the end applied to the cement to have a reduced diameter portion relative to the rest of said tool to

focus the methanical vibrations upon the area of cement to be melted.

11. The method of claim 10, which further comprises obtaining increased shearing of the melted cement while the tool is rotated by the reduced diameter portion of the elongated hollow tool as forms a semicircular trough having longitudinally running edges.

12. The method of claim 9, which further comprises generating rotational forces by a motor and transmitting said forces to said vibration source and to said elongated hollow tool for rotation thereof.

13. The method of claim 8, which further comprises cooling the elongated hollow tool and damping lateral vibrations at the end of said hollow tool.

14. The method of claim 13, which further comprises irrigating the area of melted cement to assist in removal of the melted cement.

15. The method of claim 13, which further comprises orienting and positioning means for cooling and dampening the hollow tool, concentrically with the aspiration means to assist in the removal of the melted cement.

16. A surgical apparatus for removing cement from bone or bone cavities comprising:

an elongated hollow tool for applying mechanical vibrations to cement present on a bone or bone cavity of a subject to melt the cement by vibration;

means for removing the melted cement from the bone or bone cavity through the elongated tool by suction or aspiration;

a handpiece having first and second ends with a first opening defined by the first end and said tool extending from said first opening;

a vibration source within the handpiece for generating mechanical vibrations in response to electrical current applied thereto, said vibration source operatively associated with the elongated hollow tool with said tool being attached to the handpiece at a point where no vibration occurs; and

means for rotation of said tool to apply shearing forces to the cement.

17. The surgical apparatus of claim 16, wherein the rotation means is operatively associated with said vibration source for rotating the elongated hollow tool about its longitudinal axis through at least one revolution, said rotating means also enabling said tool to apply shear forces to said cement.

18. The surgical apparatus of claim 17, wherein the opening of the elongated hollow tool at the end applied to the cement to has a reduced diameter portion relative to the rest of said tool.

19. The surgical apparatus of claim 18, wherein the reduced diameter portion of the elongated hollow tool forms a semicircular trough having longitudinally running edges for shearing the cement.

20. The surgical apparatus of claim 17, wherein said rotation means comprises a motor for generating rotational forces and means for transmitting said

forces to said vibration source and to said elongated hollow tool for rotation thereof.

21. The surgical apparatus of claim 16, wherein said vibration source includes:

a tubular piezoelectric crystal having means for electrical contact;

a union member for connecting said crystal to said elongated hollow tool and having a central passage therethrough, communicating with the elongated hollow tool; and

a hollow stem disposed inside said crystal, extending opposite from said elongated hollow tool.

22. The surgical apparatus of claim 21, wherein the stem has a length which is not resonant at the operating frequency of the crystal, and the elongated hollow tool means has a length of $\Gamma/4 + n\Gamma/2$ where n is 0 or an interger and $\Gamma=f/c$ where f is the frequency of operation and c is the velocity of extensional waves in said elongated hollow tool.

23. The surgical apparatus of claim 17, further comprising:

means for cooling and damping lateral vibration at the end of said hollow tool to assist in removal of the melted cement.

24. The surgical apparatus of claim 23, wherein the means for cooling and damping is oriented and positioned concentrically about the aspiration means.

25. The surgical apparatus of claim 22, wherein said cooling and damping means comprises:

a hollow sleeve having first and second ends surrounding the elongated hollow tool defining an interspace between said tool and said sleeve, said sleeve first end communicating with the first opening in the handpiece, and said hollow tool extending beyond said sleeve second end, wherein a portion of the hollow tool at the end contacting the cement is cut away to define a trough shape at the end, with said cut away beginning inside the second end of the sleeve; and

a hollow tube disposed inside said hollow stem defining a second interspace between said tube and said stem, said tube communicating with said central passage for the passage of aspirated material therethrough, and said second interspace communicating with said first interspace through cooling ports defined by the union member for the passage of cooling and damping fluid therethrough.

26. The surgical apparatus of claim 25, wherein the stem has a length which is not resonant at the operating frequency of the crystal, and the elongated hollow tool means has a length of $\Gamma/4 + n\Gamma/2$ where n is 0 or an interger and $\Gamma=f/c$ where f is the frequency of operation and c is the velocity of extensional waves in said elongated hollow tool.

27. A surgical instrument comprising:

a handpiece;

a vibration source within the handpiece for generating mechanical vibrations in response to current applied thereto;

elongated tool means operatively associated with said vibration source and attached to said handpiece at a point where essentially no vibrational motion occurs; said tool means extending away from said

handpiece to a work site, whereby vibration of said tool means causes disintegration and removal of hydrated biological material;

means operatively associated with said vibration source for rotating said elongated tool means about its circumference through at least one revolution, said rotating means enabling said elongated tool means to remove non-hydrated biological material;

means for irrigating said work site with fluid to assist in withdrawing removed biological material therefrom; and

aspiration means for withdrawing irrigation fluid and removed biological material from said work site.

28. The instrument of claim 27 wherein said elongated tool means includes a bevelled tip for providing increased shearing of biological material.

29. The instrument of claim 27 wherein said elongated tool means includes a closed tip portion having at least one aperture spaced therefrom to form a window in said tool means which facilitates further removal of biological material.

30. The instrument of claim 27 further comprising a support structure located within said handpiece for mounting said vibration source and rotating means and capable of independent longitudinal movement relative to said handpiece.

31. The instrument of claim 30 wherein said vibration source includes a tubular piezoelectric crystal having electrodes on inner and outer surfaces thereof; a union for connecting said crystal to said

elongated tool means; and a stem extending towards said rotating means.

32. The instrument of claim 31 wherein said rotating means comprises a motor for generating rotational forces and means for transmitting said forces to said vibration source stem and to said elongated tool means for rotation thereof.

33. The instrument of claim 32 wherein the stem has a length which is not resonant at the operating frequency of the crystal, and the elongated tool means has a length of $\Gamma/4 + n\Gamma/2$ where n is 0 or an integer and $\Gamma=f/c$ where f is the frequency of operation and c is the velocity of extensional waves in said tool means.

34. The instrument of claim 33 which further comprises means for electrically insulating each of said piezoelectric crystal and said motor from said stem and union.

35. The instrument of claim 34 wherein said insulating means comprises ceramic spacers and further comprising means for energizing said elongated tool means to supply current for cauterizing biological material that is not removed.

36. The instrument of claim 35 wherein said energizing means comprises a spring member connected to a current source and contacting said stem through bearing means.

37. The instrument of claim 27 wherein said vibration source means includes a piezoelectric disk having electrodes on opposite faces thereof.

38. The instrument of claim 27 further comprising an elongated sheath for surrounding said elongated tool means.

39. An endoscopic ultrasonic aspirator comprising the surgical instrument of claim 39 and further comprising means for viewing said work site from said handpiece.

40. The aspirator of claim 39 wherein said viewing means further comprises means for illuminating said work site to facilitate viewing thereof.

41. The aspirator of claim 39 wherein said viewing means is located within said sheath.

42. The aspirator of claim 39 wherein said sheath includes a hood member at the forward end thereof to assist in obtaining an unobstructed view of the work site through said viewing means.

43. The instrument of claim 27 wherein the rotating means is capable of rotating the elongated tool in either clockwise or counterclockwise directions.

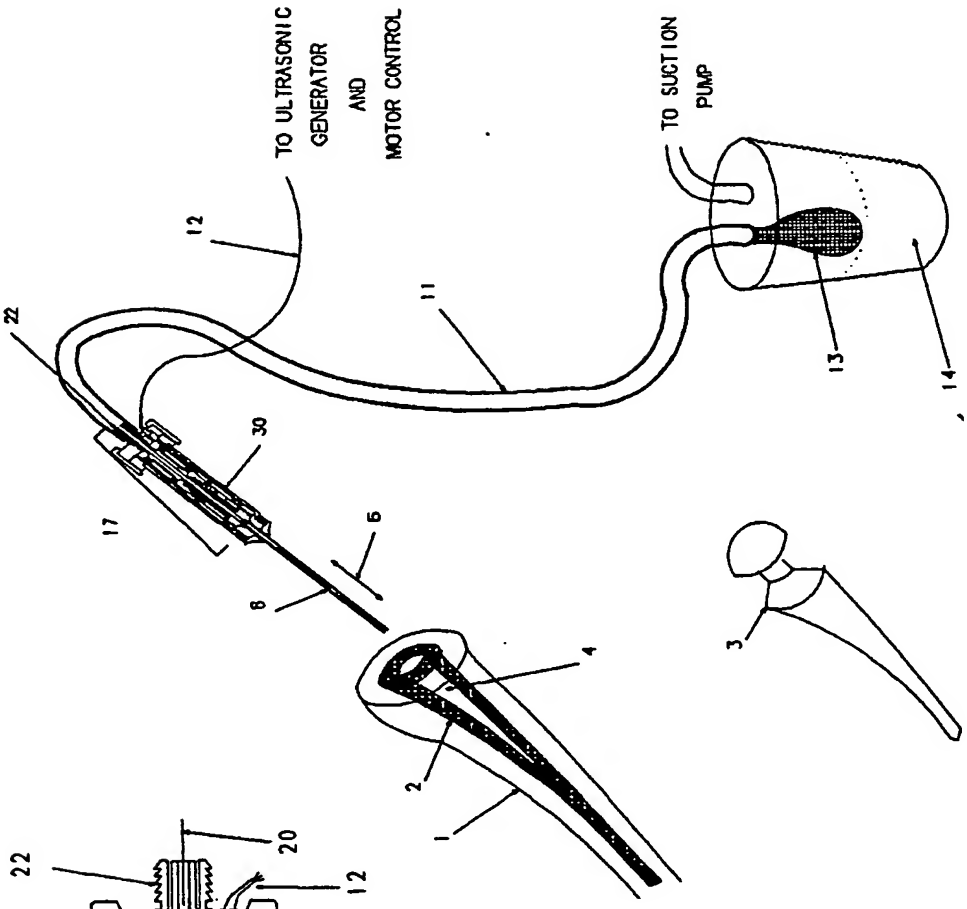


FIGURE 1

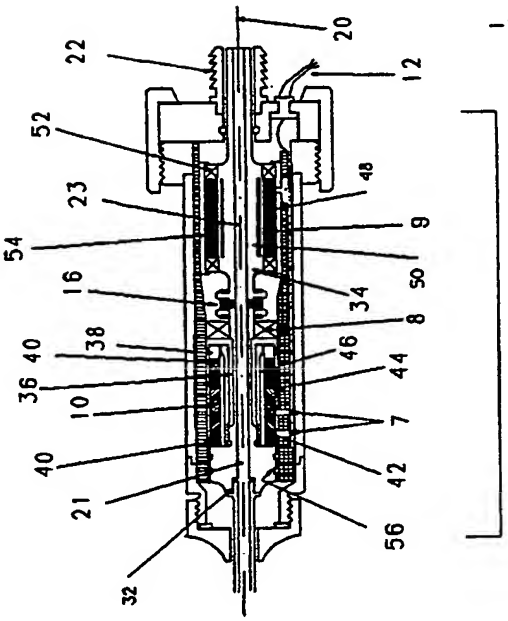


FIG. 3

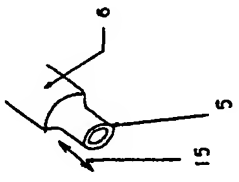


FIG. 5a

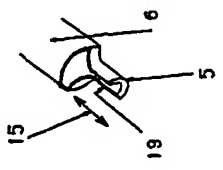
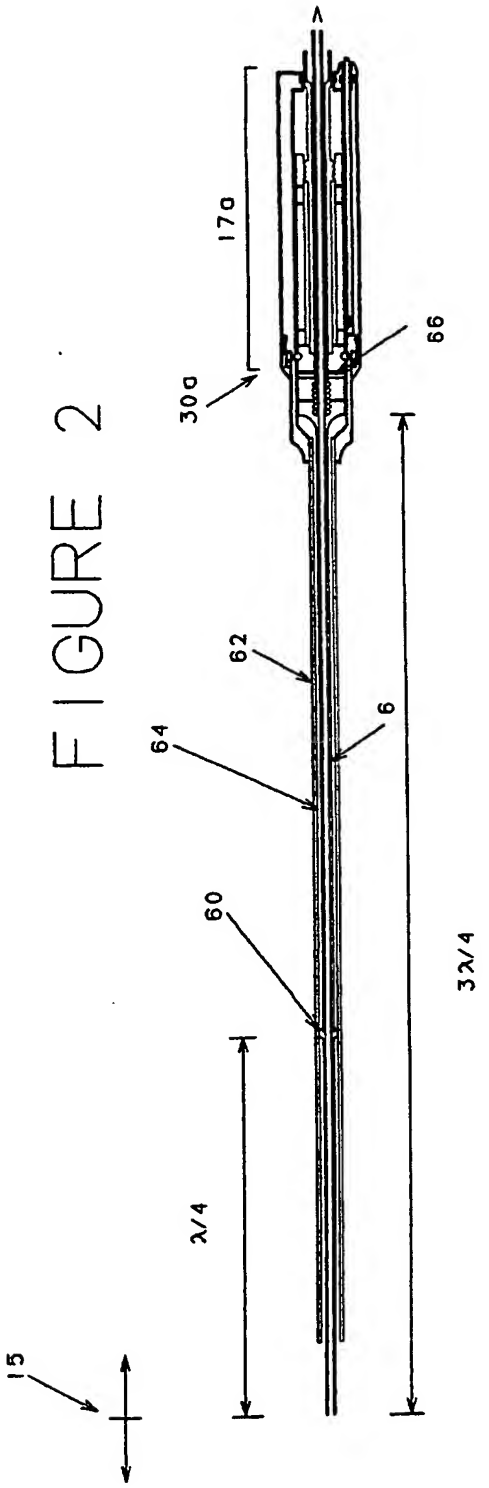
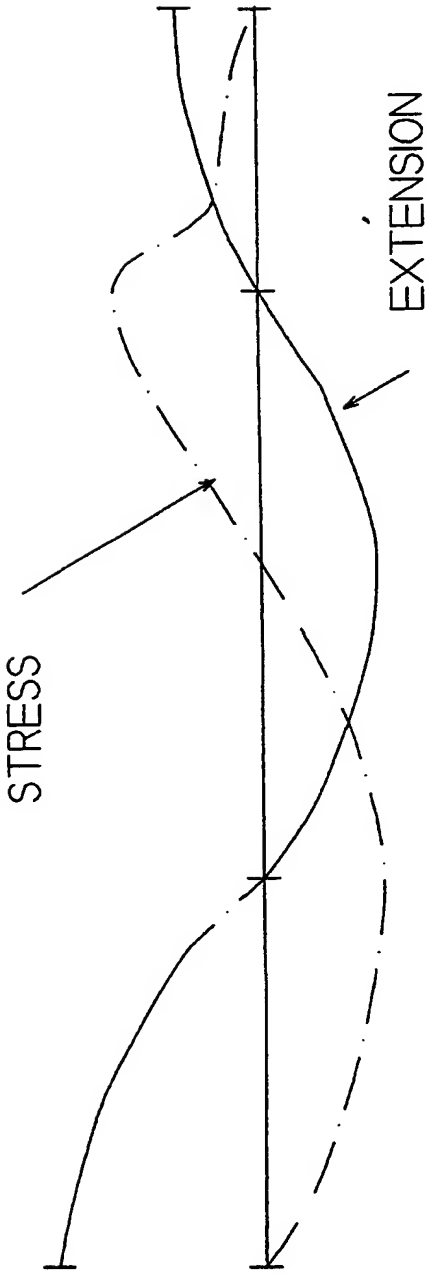


FIG. 5b

FIGURE 2





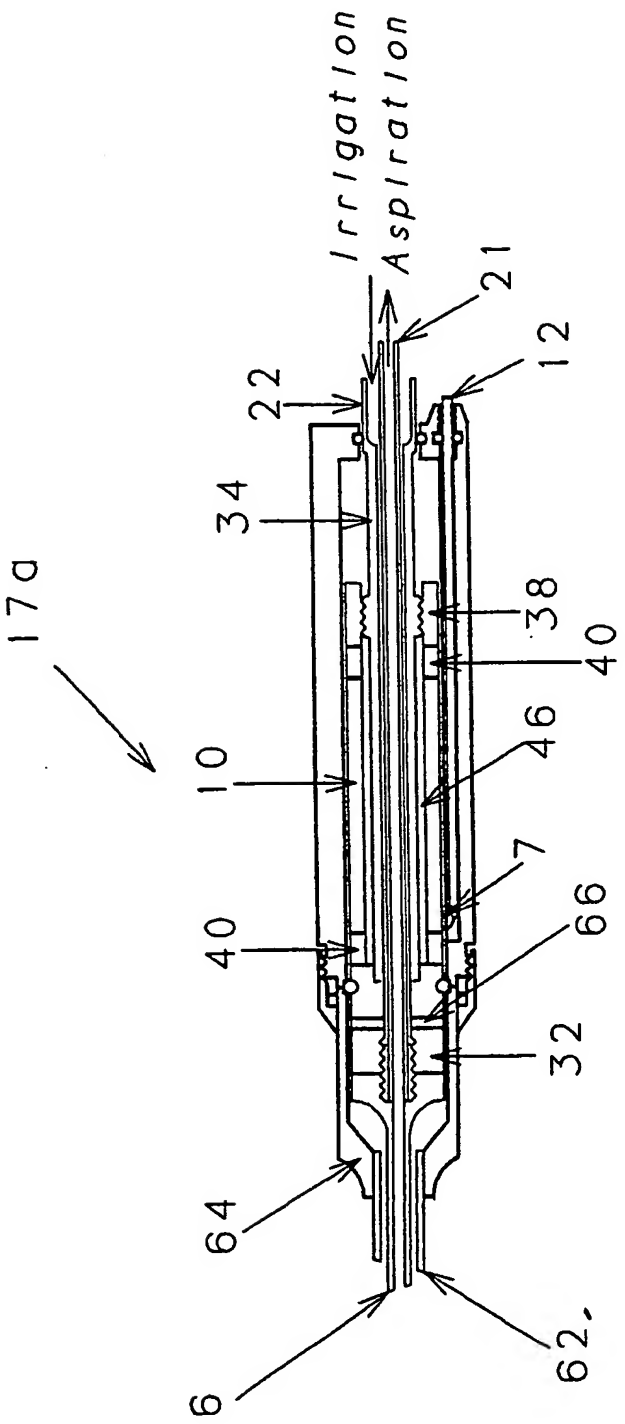

Irrigation
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Figure 4

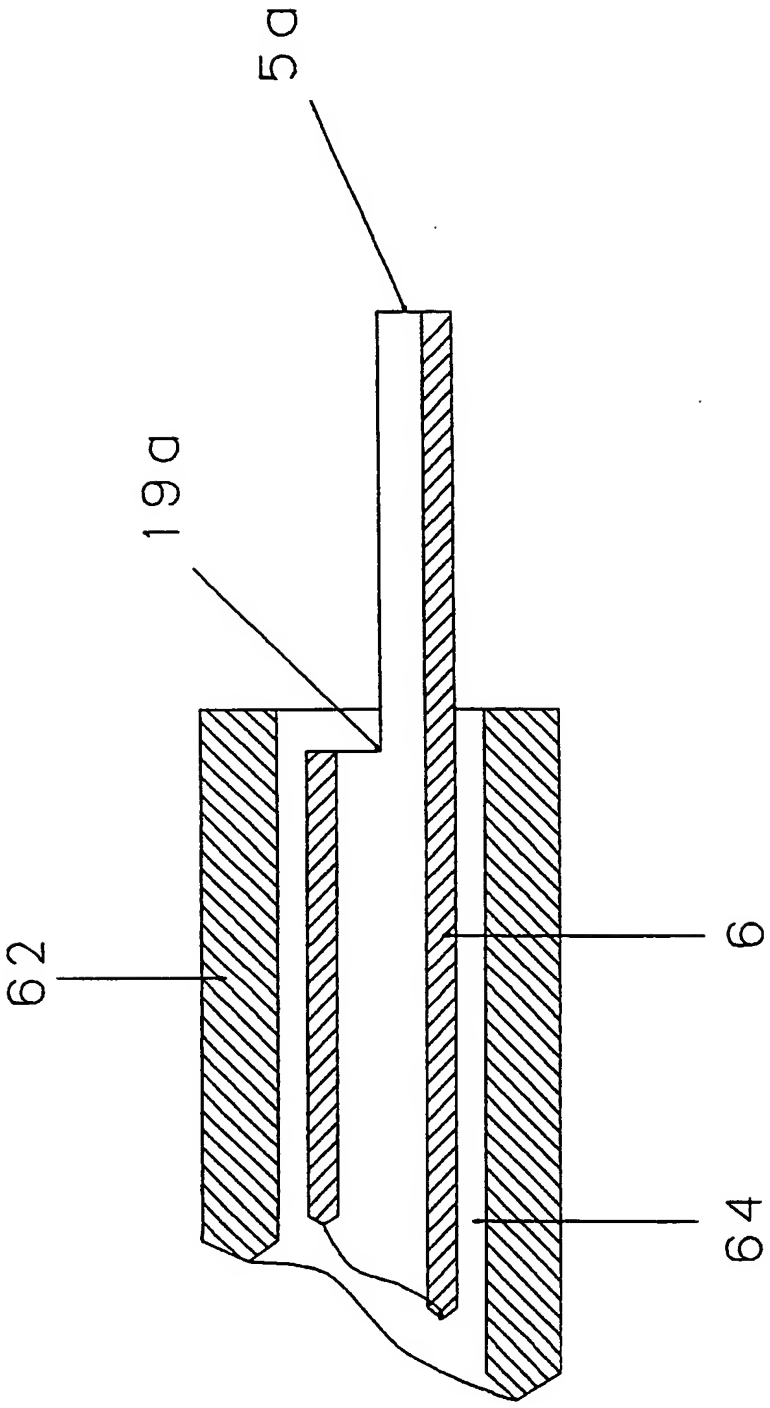


Figure 6

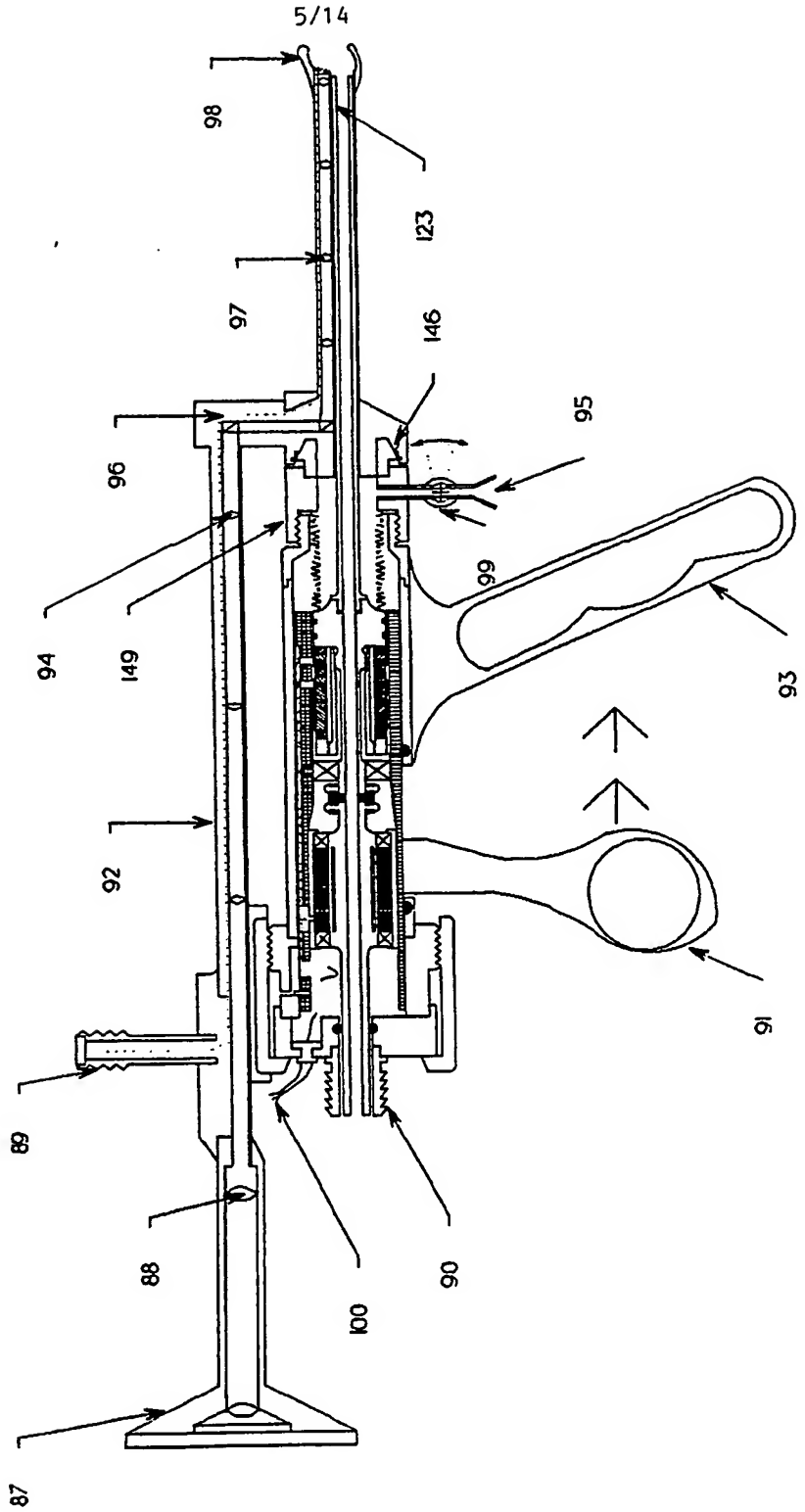


FIGURE 7

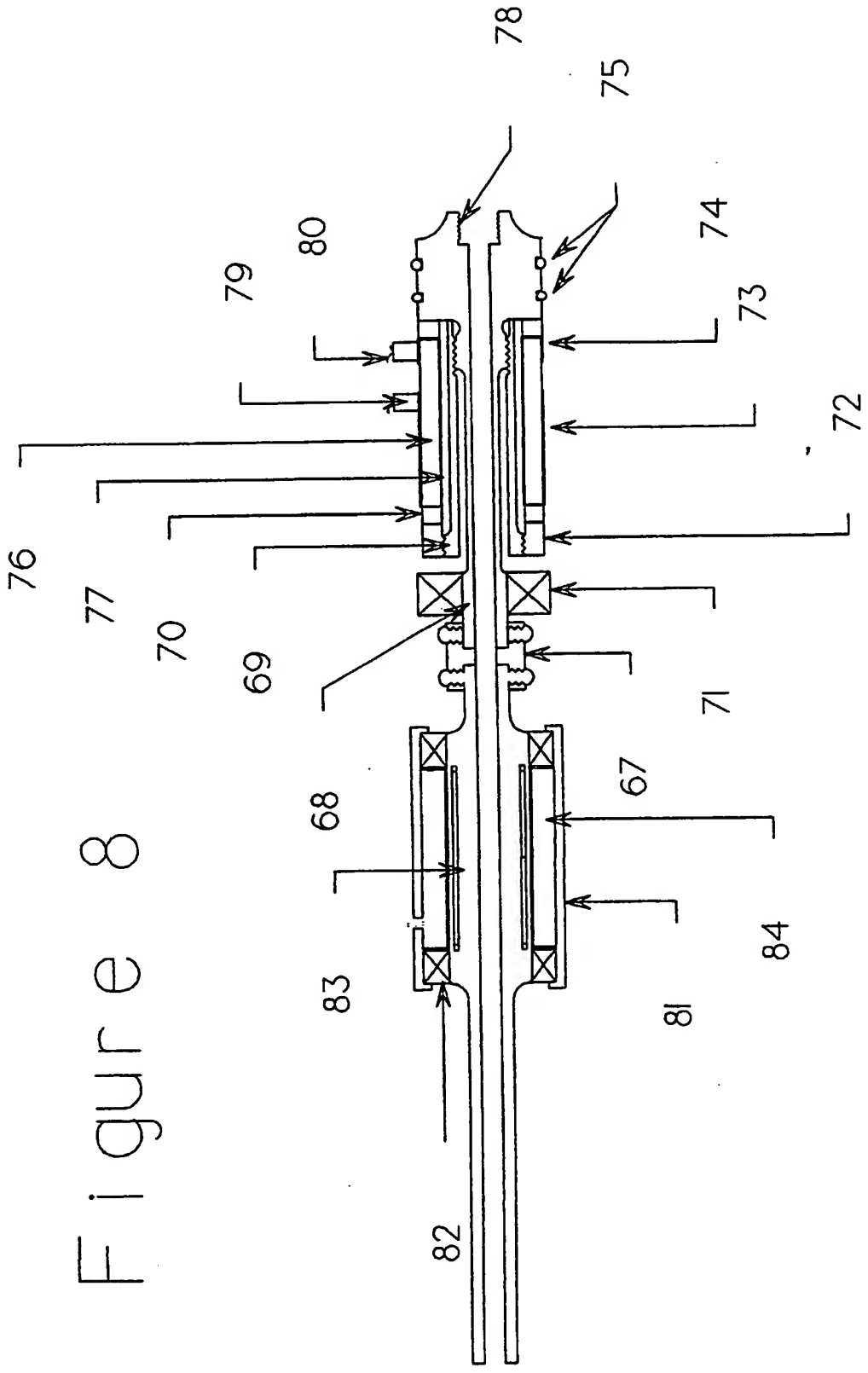
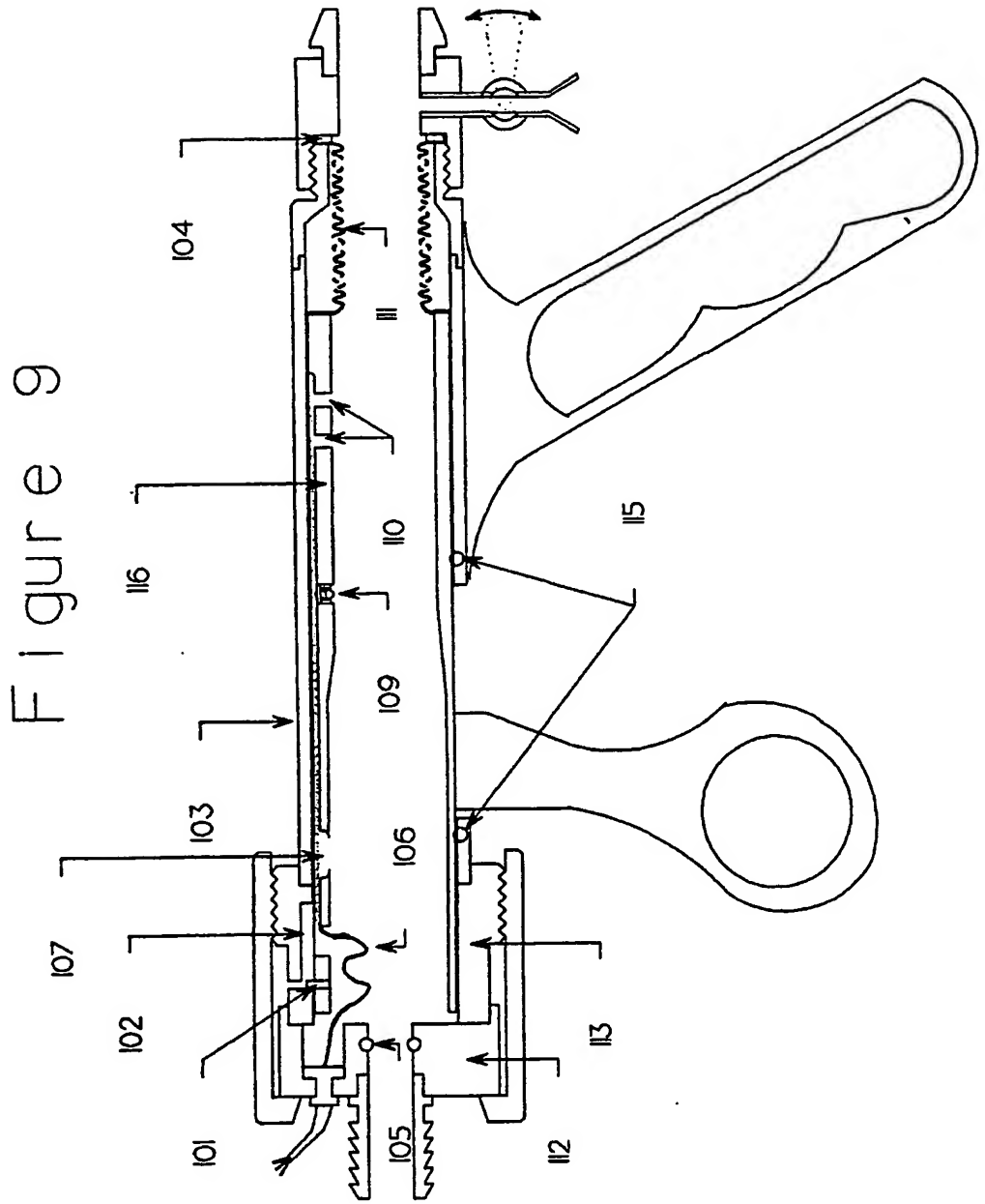


Figure 8

Figure 9



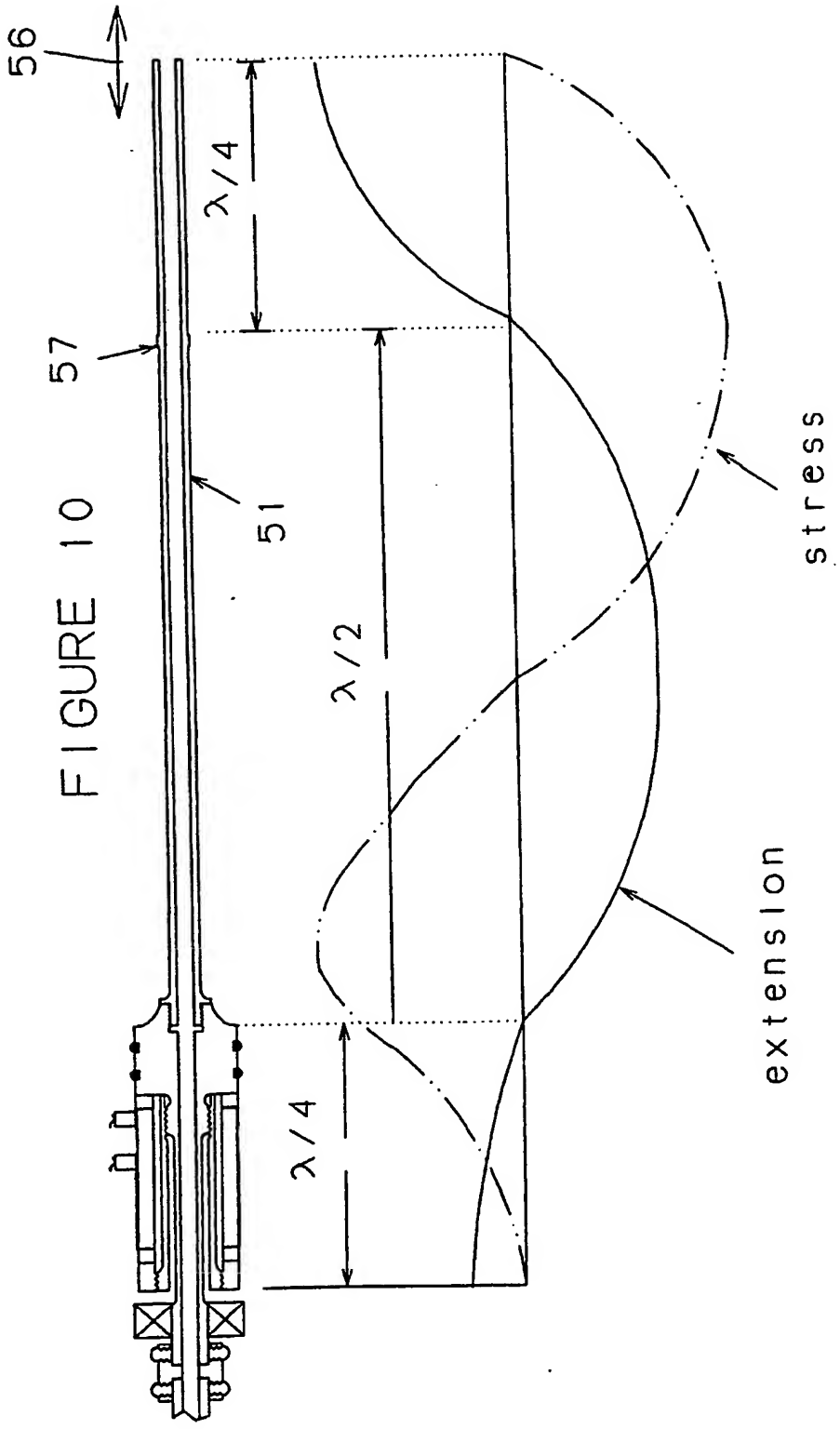


FIGURE 10

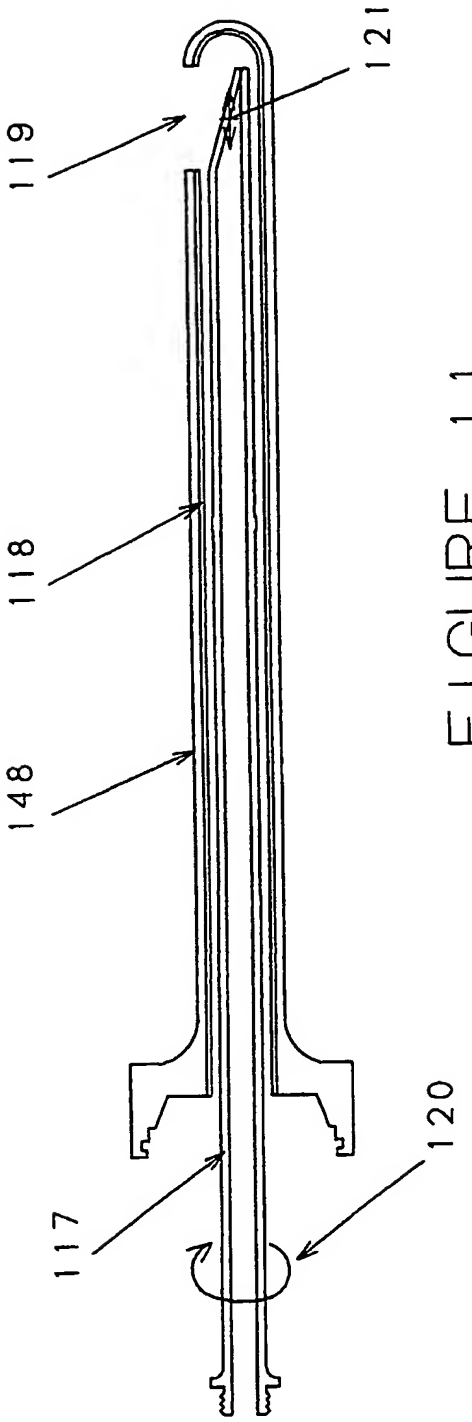


FIGURE 11

FIG. 12A - Prior Art

FIG. 12A4

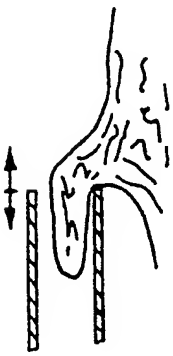


FIG. 12A3

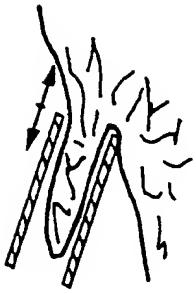


FIG. 12A2

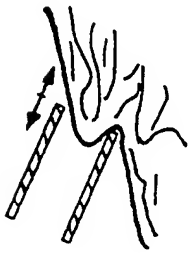


FIG. 12A1

FIG. 12B - New Invention

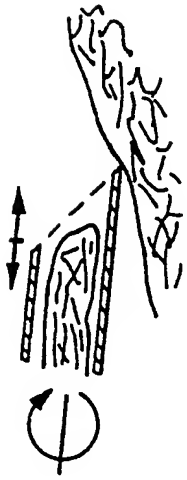


FIG. 12B4

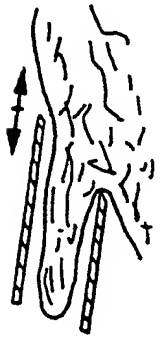


FIG. 12B3

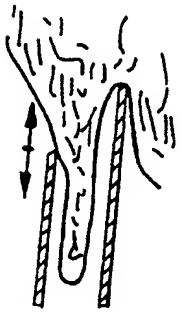


FIG. 12B2

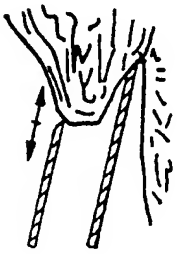


FIG. 12B1

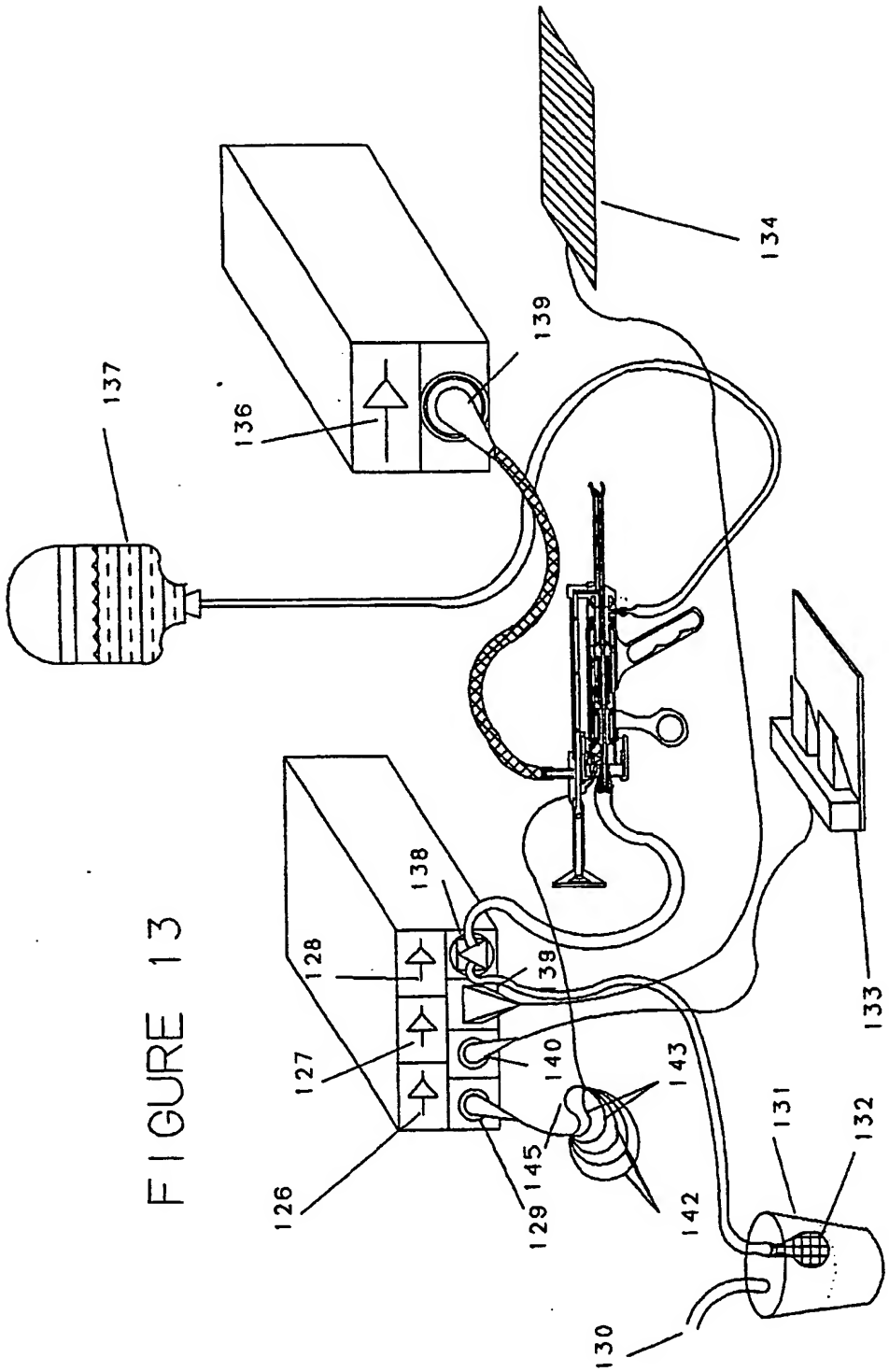

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FIGURE 13

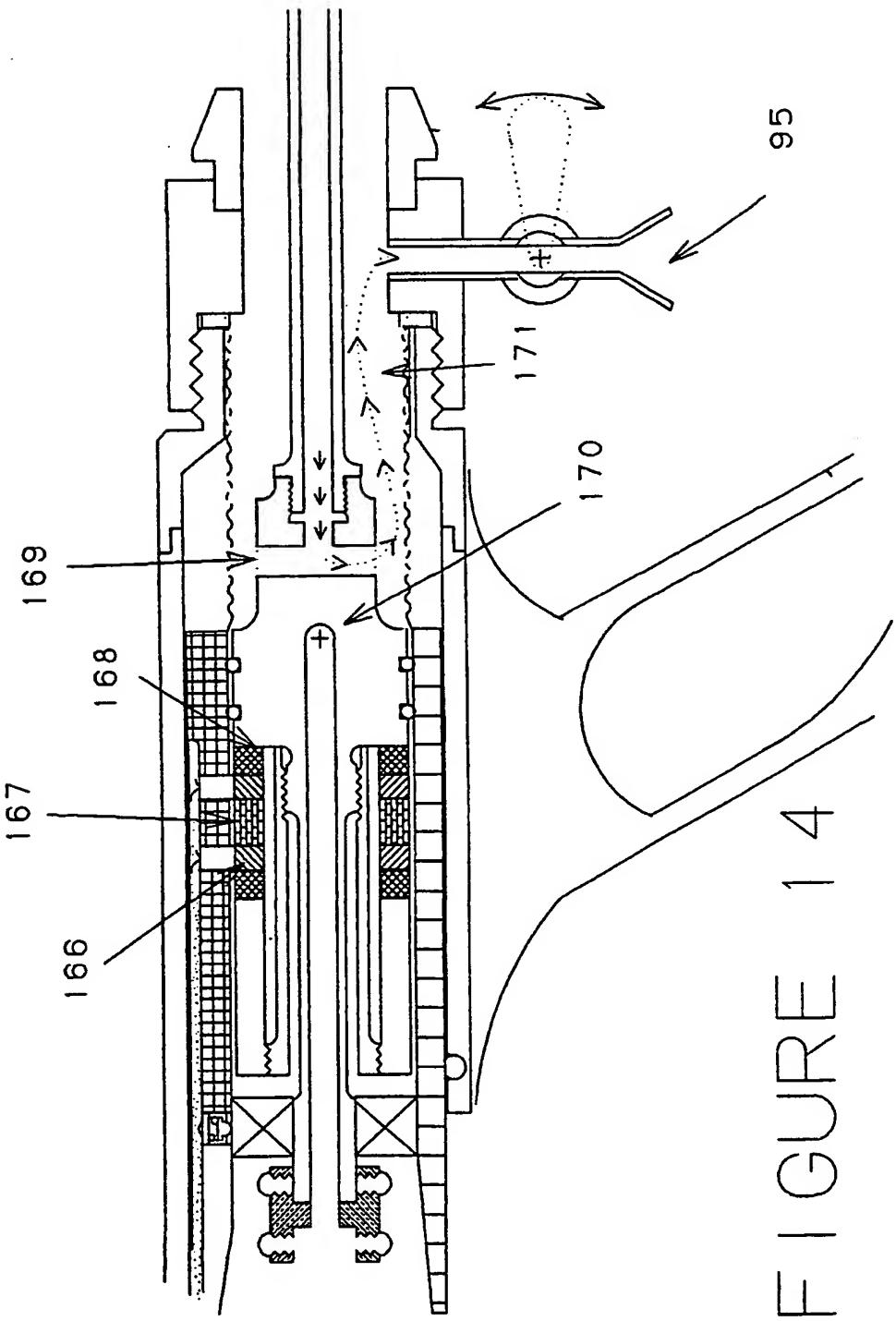


FIGURE 14

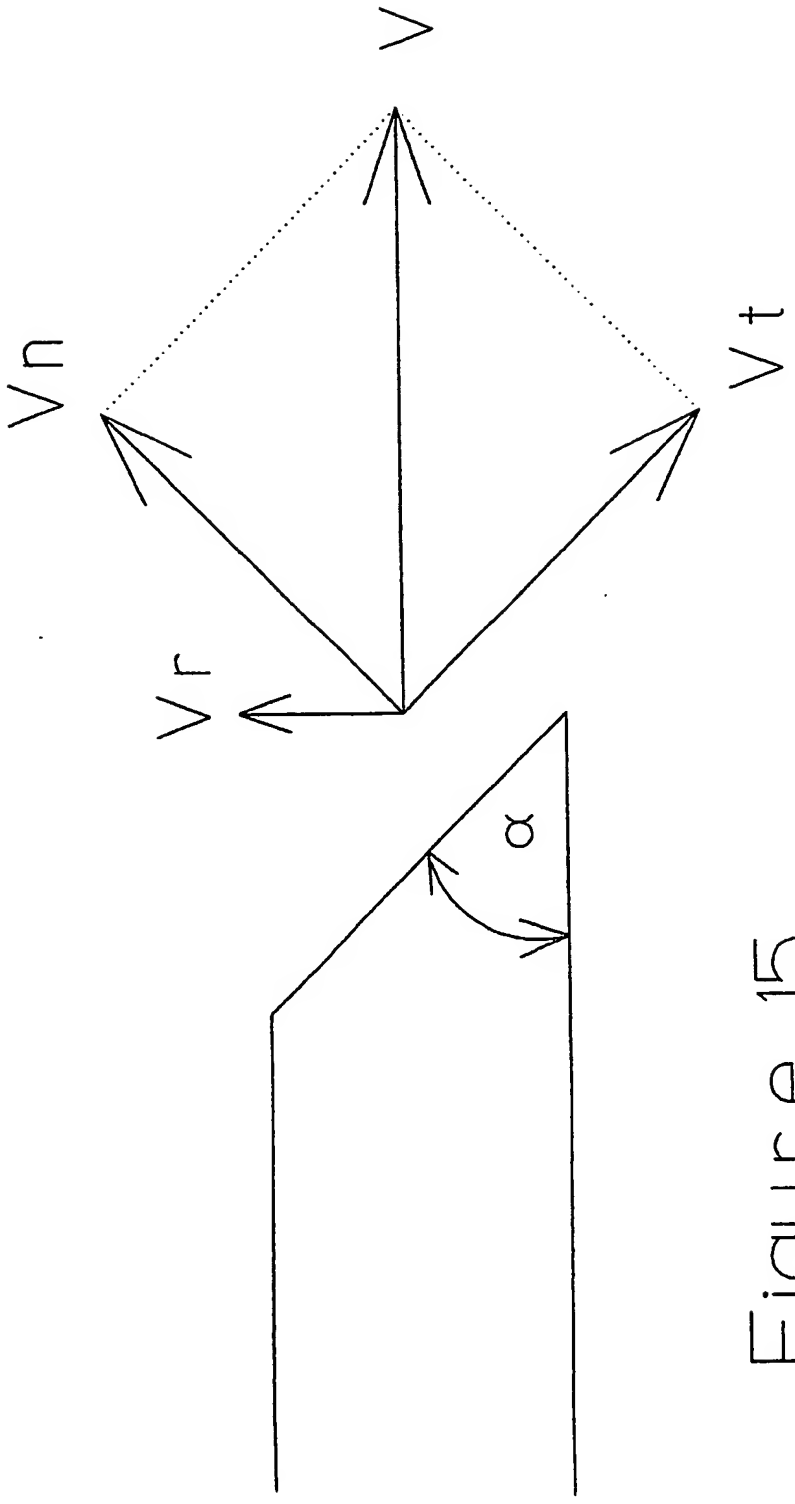
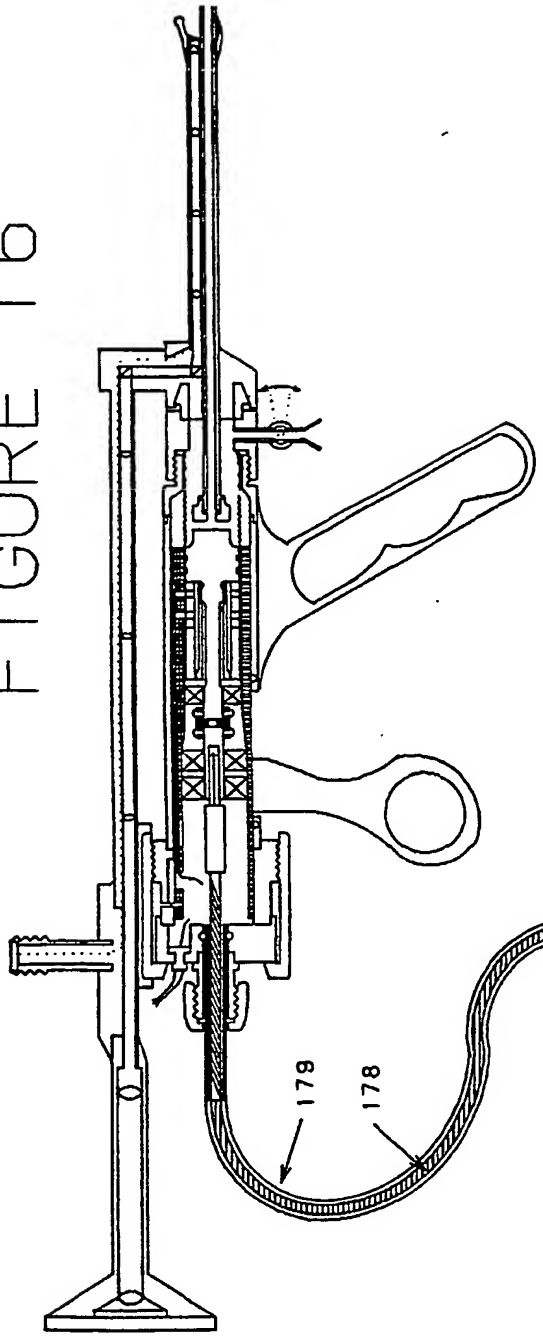


Figure 15

FIGURE 16



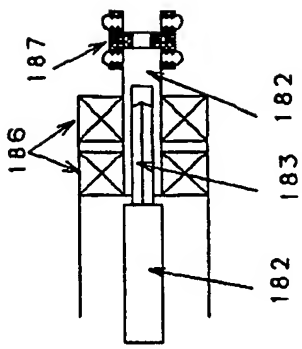


FIGURE 18

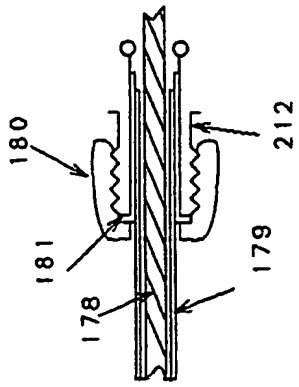


FIGURE 17

INTERNATIONAL SEARCH REPORT

International Application No PCT/US90/06737

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61B 17/56; A61H 1/00
US CL.: 604/22; 606/71; 128/24AA

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols		
US	128/24AA	604/22,27,28 35,43	606/46,128,169,170 171,174,180

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X Y	US, A, 4,428,748 (PEYMAN et al.) 31 January 1986 See entire document.	27-32,37 5,9-21,23,24
X Y	US, A, 4,248,232 (ENGELBRECHT et al.) 03 February See entire document.	1-4,6-8 5,9-21,23,24
Y	US, A, 4,603,694 (WHEELER) 05 August 1986 See figure 6.	11,19

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
25 JANUARY 1991	25 FEB 1991
International Searching Authority [1]	**Signature of Authorized Officer [20]**
ISA/US	KEVIN PONTIUS

Form PCT/ISA/210 (second sheet) (May 1986)